

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/29/2019
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 450193 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 04/05/2019 |
| NAME OF PROVIDER OR SUPPLIER CHI ST LUKE'S HEALTH BAYLOR COLLEGE OF MEDICINE ME | | | STREET ADDRESS, CITY, STATE, ZIP CODE 6720 BERTNER HOUSTON, TX 77030 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE | |
| A 000 | <p>INITIAL COMMENTS</p> <p>Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> <p>An onsite unannounced certification survey was conducted to determine the facility's compliance with the federal requirements set forth in the Medicare Conditions of Participation set forth at 42 CFR Part 482. An entrance conference was conducted on March 25, 2019 at 8:15 am in the Administrative Board Room with the facility's Administrative Staff. A brief introduction and explanation of the survey process was provided with an opportunity for questions and discussion. At 9:15 am, an entrance conference was conducted in the D.A. Cooley Auditorium with the facility's Administrative Staff, Department Directors, Medical Staff, Nurse Managers, and the full survey team. The survey process was discussed with all attendants. An opportunity was also provided for questions and discussion.</p> <p>An exit conference was conducted on 4/4/2019 with hospital leadership and staff in the D.A. Cooley Auditorium at 3:00 pm. The preliminary</p> | A 000 | | | |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| A 000 | <p>Continued From page 1</p> <p>findings were explained and an opportunity was given for questions and discussion. The next steps in the survey process were explained. An opportunity was given for the facility to provide evidence of compliance with those requirements for which non-compliance had been found during the survey. No further evidence was provided.</p> <p>The following deficient practices were identified under the following Conditions of Participation and were determined to pose Immediate Jeopardy to patient health and safety, and placed all patients at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>CFR 482.13 Patient Rights CFR 482.28 Food and Dietetics CFR 482.42 Infection Control</p> <p>Food and Dietetics</p> <p>The surveyor determined through observation, record review, and interview, the following conditions in the dietary department were identified:</p> <p>On the morning of 3/25/2019:</p> <p>The walk-in refrigerator #68, which contained milk products used for patients, was not maintaining adequate temperatures, placing patients at risk of receiving spoiled dairy products, which could result in diarrhea, vomiting, and severe abdominal pain. The milk products had been distributed to the patient nutrition rooms on approximately 38 floors of the facility as well as</p> | A 000 | | | |

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| A 000 | <p>Continued From page 2</p> <p>being served in the cafeteria to the public and being used in food preparation.</p> <p>On the morning of 3/26/2019:</p> <p>A.) The facility's two large mechanical dish washers were not working properly, building up copious amounts of steam that was condensing and dripping off the dirty ceiling tiles onto the cleaned dishware. This placed the patients at risk of eating off of contaminated dish wares. Surveyor noted water of unknown origin was draining from a ceiling tile in the pots and pans dish washing area that posed a risk of clean pots and pans being contaminated.</p> <p>B.) The kitchen's sewage was backing up into the patient food production areas, placing patients at risk of consuming contaminated foods possibly resulting in diarrhea, vomiting and severe abdominal pain. Review of work orders revealed an ongoing problem from 1/8/19 to the time of the survey.</p> <p>C.) The dirty pots and pans available for use by kitchen staff were stored wet, vegetables with molds were available for use, and the floors and kitchen equipment were coated with dirty grease and old food particulates creating an unsanitary environment.</p> <p>These deficient practices were determined to pose an Immediate Jeopardy to patient health and safety, and placed all patients at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> | A 000 | | | |

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| A 000 | <p>Continued From page 3</p> <p>The facility's President/Chief Executive Officer was informed at approximately 11:15 am on 3/26/2019 of these findings. The facility was given an opportunity to provide a plan of removal for the Immediate Jeopardy findings. The facility provided a plan of removal on 4/1/2019 and the Immediate Jeopardy was abated after surveyor verified the implementation.</p> <p>The facility's Plan of Removal of the Immediate Jeopardy in Dietary was as follows:</p> <p>A.) CORRECTIVE ACTION --The dishwasher and the pot washer were immediately removed from service. Facilities placed a sign indicating both pieces of equipment were out of commission awaiting repair.</p> <p>--Use of disposable dishware and serving containers was immediately implemented.</p> <p>--A three-sink station for manually cleaning and sanitizing of non-disposable wash pots and skillets was implemented. A real time audit tool checklist was utilized to observe staff performing cleaning and sanitizing.</p> <p>--The "Gold Check Audit" was completed jointly by a member of the contracted nutrition services and a member of the hospital senior leadership team. Results of the "Gold Audit Checklist" were reported to the Chief Executive Officer.</p> <p>--Effectively immediately, two new positions have been created which includes one individual responsible for implementation of food sanitation</p> | A 000 | | | |

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| A 000 | <p>Continued From page 4</p> <p>standards and the other position responsible for infection control practices specific to the kitchen.</p> <p>--The Facilities work ticket prioritization process has been reviewed and approved by the hospital COO.</p> <p>--Open maintenance logs for the kitchen have been reviewed and prioritized for high risk areas with response times identified.</p> <p>--Electronic temperature track system is being installed on all freezers and refrigerators. The notification when temperatures are out of range are being directed to the Facilities Leadership and Dietary Services Leadership.</p> <p>--Maintenance has created a report that tracks priority of work orders and response time. Facilities Leadership is now sending a weekly report to the Vice President of Operations, the CFO and the CAO.</p> <p>--A complete assessment of all kitchen equipment has started which includes the proper categorization of equipment, operational functionality and physical condition, work order history review, recommendation of repair, and recommendation of replacement. This will be submitted to the CAO by April 12th</p> <p>--All work orders submitted by the kitchen for the past three months were reviewed and issues involving repairs were identified. All identified items are in process of being repaired.</p> <p>--The Hospital CFO and CAO have met with the contracted dietary services to evaluate the effectiveness of the current leadership.</p> | A 000 | | | |

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| A 000 | <p>Continued From page 5</p> <p>--An external company has been contracted to conduct an evaluation of dietary services.</p> <p>--"Refrigerator and Freezer Monitoring - Patient Care" policy was updated to reflect the correct way to move/dispose of food when the refrigerator or freezer are out of range.</p> <p>EDUCATION--Signage has been placed on designated equipment as not in use Dietary staff received education each shift until all were notified the equipment was not in use.</p> <p>--The organization notified hospital leadership and staff of the use of disposable dishware until further notice.</p> <p>--Patients were notified of the use of disposable dishware by a letter attached to their meal tray.</p> <p>--The Operations Manager of Nutrition Services provided training starting with the current shift and was continued each shift until all Dietary staff were trained on the manual cleaning process.</p> <p>--The Chief Executive Officer set expectations with the contracted nutrition services Leadership Team of the escalation process in the hospital, expectations of performance to the contract, the "Gold Check Audit" requirements and reporting any concerns or repairs as needed immediately through the established work order process. In the event the request represents a potential patient safety issue the leadership team was instructed to follow the hospital's established chain of command until the issue is resolved up to and including notification to the CEO.</p> | A 000 | | | |

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| A 000 | <p>Continued From page 6</p> <p>--In-service occurred with Dietary Leadership on the expectations for the process of disposing of food when temperatures go out of range which included the revisions to the "Refrigerator and Freezer Monitoring - Patient Care".</p> <p>--Members of the leadership team for Facilities has been educated on expectations for priority of work orders and timeframes by the Chief Administrative Officer and Division Director of Facilities.</p> <p>MONITORING COMPLIANCE--Infection Control and Chief Administrative Officer (CAO) visually confirmed the dishwasher and pot washer have been identified as nonoperational.</p> <p>--The pot washer parts are being sourced and awaiting arrival. Repair services contracted by the hospital completed the repair of the dishwasher. Infection Control and the CAO confirmed the equipment was repaired and properly functioning prior to resuming operations.</p> <p>--A member of the Quality or Infection Control team conducts direct observations three times a shift of the manual cleaning process to ensure it has been completed correctly per the standard operating procedure. Three times a shift 30 utensils, pots or pans manually washed are inspected by a member of the of Quality or Infection Control team to ensure they are free from debris. This audit will continue until the dishwasher and the pot washer is fully functional.</p> <p>--The "Gold Check Audit" was completed by the Operations Manager of Nutrition Services and submitted to the Chief Executive Officer. Action</p> | A 000 | | | |

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| A 000 | <p>Continued From page 7</p> <p>plans were developed are monitored weekly through the Executive Quality Council until compliance with the contract is achieved and sustained. Once compliance is sustained, the "Gold Check Audit" will be completed per the contract guidelines to ensure performance expectations are continuously met. The results will be reported to the Hospital's Management Review Committee, Medical Executive Committee and the Board of Trustees on a semi-annual basis. Currently open maintenance work orders are reviewed weekly for appropriate classification, response time and completion by Senior Leadership. Weekly the data is aggregated and reported to the Vice President of Operations to identify trends and develop action plans.</p> <p>--All kitchen work orders are audited weekly to review appropriate prioritization, work quality, documentation and timeliness of response until 100% compliance is sustained for 2 months. When compliance is sustained the auditing process will be reviewed through the 50 random audits per week process.</p> <p>--Weekly, facility wide 50 random work orders are audited weekly to review appropriate prioritization, work quality, documentation and timeliness of response on an ongoing basis. Data will be aggregated weekly and reported to the Executive Quality Council weekly until two months of compliance is sustained. When 100% compliance is sustained for two months the monitoring will continue on an ongoing basis monthly and oversight of compliance will transition to the Vice President of Operations and reported quarterly to the Environment of Care and Safety Committee. If compliance is not sustained auditing will go to</p> | A 000 | | | |

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| A 000 | <p>Continued From page 8</p> <p>weekly and progress back to monthly when compliance is sustained for two months.</p> <p>B.) CORRECTIVE ACTION --A Contracted Company was obtained to assess all sewer pipes in the kitchen.</p> <p>--Sewer pipes were snaked and blockages removed.</p> <p>--Sewer pipe sections needing repair were identified with a plan approved to replace the sections within the next 30 days.</p> <p>EDUCATION--All Dietary staff was provided education by a Leader in Facilities regarding the daily maintenance of the sewer pipes and how to escalate concerns.</p> <p>--All Facilities staff was provided education by the Director of Facilities regarding the expectations for responding to the kitchen work orders or requests.</p> <p>MONITORING COMPLIANCE--Daily a member of the Dietary staff inspects the drains for visible blockages. If blockages are identified Facilities will be immediately notified and a work order placed.</p> <p>--Daily a member of the Facilities staff uses an approved biodegradable solution to pour down the drains to keep blockages from occurring. This will continue until the pipes have been repaired and a preventative maintenance schedule has</p> | A 000 | | | |

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| A 000 | <p>Continued From page 9</p> <p>been created that reflects expert recommendations for keeping the sewer maintained. Compliance to maintenance schedule will be reported monthly to the Vice President of Operations and quarterly to the Environment of Care and Safety Committee.</p> <p>--A member of the facilities Team is inspecting the Kitchen drains for visible blockages two times per shift. This will continue until the pipes have been repaired and a preventative maintenance schedule has been created that reflects expert recommendations for keeping the sewer maintained. Compliance to maintenance schedule will be reported monthly to the Vice President of Operations and quarterly to the Environment of Care and Safety Committee.</p> <p>--An Executive Quality Council (EQC), chaired by the President or Senior Leader designee will meet weekly to provide oversight of the compliance with the monitoring measures. This council will continue to oversee the monitoring measures until all action items are completed and compliance is sustained for 2 months.</p> <p>-- Individual deficiencies will be reported to the appropriate supervisor or manager. Any deficiencies will be addressed with the individual through training, reeducation and/or following the human resources corrective action process.</p> <p>C.) CORRECTIVE ACTION--Facilities removed ceiling tiles for inspection and assessment of the exhaust vent was conducted. A condensation trap was reinsulated to address the leak. Ceiling tiles were replaced after the work was completed.</p> | A 000 | | | |

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| A 000 | <p>Continued From page 10</p> <p>--A facility and infection control assessment of the entire kitchen was performed.</p> <p>--All rusted light fixtures were removed and replaced.</p> <p>--The rusted, damaged, and soiled equipment were discarded.</p> <p>--Cooler 68 was removed from service with signage placed as well as a lock to signify it is not in use.</p> <p>--Visual inspections by a member of the Quality or Infection Control Team of all dishes and materials used in the kitchen were completed prior to being returned back to service to ensure they meet cleanable standards and were free of debris, grease or carbon build up.</p> <p>EDUCATION--All Facilities staff was provided education by the Director of Facilities regarding the expectations for responding to the kitchen work orders or requests.</p> <p>--The Dietary Leadership received education through completion of the "Golden Audit Checklist" Tool on the expectations for the kitchen to meet infection control standards.</p> <p>--Dietary staff received education each shift until all were notified of Cooler 68 no longer available for use.</p> <p>MONITORING COMPLIANCE--Audits are completed three times a week by members of the</p> | A 000 | | | |

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| A 000 | <p>Continued From page 11</p> <p>Infection Control or Quality Team to include direct observations of cleanliness of pots/pans, equipment working properly, and infection control practices are in place until 100% compliance achieved. When compliance is achieved, monitoring will continue weekly until compliance is sustained for 2 months. When compliance is sustained for 2 months auditing will occur monthly. If compliance is not sustained auditing will go back to three times a week and progress back to monthly as compliance is sustained. Results are provided to the Dietary Leadership and Vice President of Operations. Quarterly results will be provided to the hospital's Management Review Committee.</p> <p>--On an ongoing basis, a member of the Dietary staff checks temperatures twice a day for all refrigerators and freezers. Any temperature out of range is reported to Facilities immediately and the Refrigerator and Freezer Monitoring-- Patient Care". Daily a member of the Dietary Leadership staff inspects the completion of this requirement. Monthly compliance is reported to the Vice President of Operations and quarterly to the Environment of Care and Safety Committee.</p> <p>--An Executive Quality Council C EQC), chaired by the President or Senior Leader designee will meet weekly to provide oversight of the compliance with the monitoring measures. This council will continue to oversee the monitoring measures until all action items are completed and compliance is sustained for 2 months.</p> <p>--Individual deficiencies will be reported to the appropriate supervisor or manager. Any deficiencies will be addressed with the individual through training, re-education and/or following the</p> | A 000 | | | |

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| A 000 | <p>Continued From page 12 human resources corrective action process.</p> <p>Infection Control</p> <p>D.) Based upon numerous observations and interviews conducted between 3/25/2019 and 3/27/2019, the facility failed to:</p> <ol style="list-style-type: none"> 1. ensure nursing staff and Environmental Services (EVS) staff practiced established infection control measures by appropriately applying and/or removing Personal Protective Equipment (PPE) when working in isolation rooms. 2. ensure that patient rooms were cleaned properly without cross contamination of surfaces and patient care equipment was properly sanitized when removed from isolation rooms. The facility also failed to ensure EVS staff terminally cleaned patient rooms upon discharge. 3. ensure staff properly disinfected transvaginal ultrasound transducers between patients. 4. maintain the sterile field in sterile pharmaceutical compounding areas. <p>These deficient practices were determined to pose an Immediate Jeopardy to patient health and safety, and placed all patients at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>The facility's President/Chief Executive Officer was informed at approximately 8:30 am on</p> | A 000 | | | |

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| A 000 | <p>Continued From page 13</p> <p>3/28/2019 of these findings. The facility was given an opportunity to provide a plan of removal for the Immediate Jeopardy findings. The facility provided a plan of removal on 4/3/2019 and the Immediate Jeopardy was abated after surveyors verified the implementation.</p> <p>The Plan of Removal was as follows:</p> <p>Wearing of PPE in Isolation Rooms</p> <p>Corrective Actions</p> <p>--A new process has been implemented where members from Infection Control, Quality, and Hospital Leadership, through direct observation, are auditing any personnel entering and exiting an isolation rooms for correct donning, doffing personal protective equipment (PPE), and cleaning of equipment. Auditors in real time are interrupting and coaching when break in process is identified.</p> <p>--Infection Prevention developed educational tools and videos on proper procedure for donning, doffing PPE and for cleaning patient care equipment when entering and exiting an isolation room as well as removal of trash.</p> <p>--The training for donning, doffing, and cleaning of equipment in an isolation room was updated to require return demonstration.</p> <p>--A competency skills fair and train the trainer program was developed and implemented for all staff entering a patient room with standardized consistent evaluations and competency assessments for wearing of PPE and cleaning of</p> | A 000 | | | |

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| A 000 | <p>Continued From page 14</p> <p>equipment when entering and exiting an isolation room.</p> <p>--New computer workstations were purchased to dedicate to isolation rooms.</p> <p>--A new isolation work process was developed for EVS to clean an isolation room. An EVS competency checklist was created and implemented.</p> <p>Education</p> <p>--Leaders were educated by infection prevention in the "Train the Trainer" education program for proper process for PPE and equipment cleaning with return demonstration competency assessment for entering and exiting isolation rooms.</p> <p>--Over two thousand six hundred staff, residents and physicians have participated in the Isolation and PPE return demonstration training by approved trainers. This will continue to occur until all staff, residents and physicians entering and exiting an isolation room have completed the return demonstration training. New Employee and physician orientation will now include return demonstration training for proper wearing of PPE and cleaning of equipment when entering and exiting an isolation room.</p> <p>--Direct observations of all staff entering isolation rooms to validate each step of the donning, doffing PPE process and equipment cleaning includes interrupting and coaching when a break in process is identified.</p> <p>--Direct observation competency assessments</p> | A 000 | | | |

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| A 000 | <p>Continued From page 15</p> <p>are conducted by EVS leadership concurrently for EVS staff entering isolation rooms to validate each step of the donning and doffing PPE process and equipment cleaning was completed.</p> <p>-- EVS Director completed the "Train the Trainer" education and return demonstration competency assessment</p> <p>--A team of 10 designated EVS staff completed the isolation room cleaning education and return demonstration competency assessment with a plan developed for training the rest of the EVS staff.</p> <p>Monitoring Compliance</p> <p>--Through direct observation, a member of the Quality or Infection Prevention team will audit 50 staff, residents or physicians weekly to validate the proper wearing of PPE and cleaning of equipment practices when entering and exiting a room in accordance with hospital policy. Data will be aggregated weekly and reported to the Executive Quality Council weekly until 2 months of compliance is sustained. When 100% compliance is sustained for 2 months the monitoring will continue on an ongoing basis monthly. The findings are reported bi-monthly to the Infection Control Committee. Results will be reported quarterly to the Quality Oversight Committee, Medical Executive Committee and the Quality Committee of the Board of Trustees.</p> <p>--Through direct observation, a member of the Quality or Infection Prevention team will audit 10 isolation room cleanings per week to validate the proper cleaning process of an isolation room. Data will be aggregated weekly and reported to</p> | A 000 | | | |

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| A 000 | <p>Continued From page 16</p> <p>the Executive Quality Council weekly until 2 months of compliance is sustained. When 100% compliance is sustained for 2 months the monitoring will continue on an ongoing basis monthly. The findings are reported bi-monthly to the Infection Control Committee. Results will be reported quarterly to the Quality Oversight Committee, Medical Executive Committee and the Quality Committee of the Board of Trustees.</p> <p>E.) On 4/1/2019 at 9:15 am, Surveyor observed RN #169 fail to follow Manufacturer's Direction for Use and the Facility's Policy and Procedure, to ensure air detectors (optical detection mechanism) was engaged during self- testing of a hemodialysis machine, prior to initiation of a patient's hemodialysis treatment, in 1 of 1 hemodialysis machines (#26) observed during self- testing. The clamp/optical detection mechanism not engaged during pre-testing safety tests, puts all hemodialysis patients who receive hemodialysis treatment in the facility at risk of air getting into patients' blood stream during hemodialysis treatment, which can result in actual harm to patients.</p> <p>These deficient practices were determined to pose an Immediate Jeopardy to patient health and safety and placed all patients receiving dialysis at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>The facility's President/Chief Executive Officer was informed at approximately 1:15 pm on 4/1/2019 of these findings. The facility was given an opportunity to provide a plan of removal for the Immediate Jeopardy findings. The facility provided a plan of removal on 4/3/2019 and the</p> | A 000 | | | |

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| A 000 | <p>Continued From page 17</p> <p>Immediate Jeopardy was abated.</p> <p>The facility's Plan of Removal of the Immediate Jeopardy for Patient Rights, Care in a Safe Setting, was as follows:</p> <p>CORRECTIVE ACTION-- Immediately, a safety alert was created by the Director of Dialysis to alert staff to the manufacturer requirements of testing and setting up the machine properly with the venous clamp and optical detector door.</p> <p>-- A hemodialysis machine pre-treatment preparation competency was updated by the Director of Dialysis to include all steps in the preparation process.</p> <p>-- Immediately, the cleaning process of equipment in between patients' competency for dialysis rooms was re-implemented by the Director of Dialysis for all applicable staff in the unit. This included a re-demonstration of each applicable staff member's knowledge of the cleaning process.</p> <p>-- Infection Prevention developed educational tools and videos on proper procedure for donning, and doffing personal protective equipment (PPE). The training for donning, and doffing was updated to require return demonstration.</p> <p>--A dialysate concentrate adjustment competency was created for return demonstration of competency with using the solution and use of PPE.</p> | A 000 | | | |

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| A 000 | <p>Continued From page 18</p> <p>EDUCATION--The Leadership Team in Dialysis and members of the Infection Control Department watched each dialysis nurse and patient care technician complete a return demonstration for the cleaning process of equipment in between patients.</p> <p>--The Leadership Team in Dialysis and members of the Infection Control Department watched each dialysis nurse complete a return demonstration for the setup of the dialysis machine. The Leadership Team in Dialysis and members of the Infection Control Department watched the dialysis nurses and patient care technicians entering and exiting dialysis rooms complete a return demonstration for the proper donning and doffing procedure for wearing of PPE which included wearing PPE at the initiation and the discontinuation of dialysis.</p> <p>--The Leadership Team in Dialysis and members of the Infection Control Department watched the dialysis nurses and patient care technicians, via return demonstration, use dialysate concentrate adjustment solution and use of PPE.</p> <p>-- New Employee orientation for dialysis personnel will now include return demonstration training for proper wearing of PPE, cleaning of equipment in between patients, and use of dialysate concentrate adjustment solution and use of PPE.</p> <p>MONITORING COMPLIANCE--Through direct observation, a member of the Dialysis Leadership will audit 30 events per week to validate the proper wearing of PPE, cleaning of equipment</p> | A 000 | | | |

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| A 000 | Continued From page 19 practices, use of dialysate concentrate adjustment solution and set up of the dialysis machine. Additionally, through direct observation, Quality or Infection Prevention team will audit 10 events per week to validate the proper wearing of PPE, cleaning of equipment practices, use of dialysate concentrate adjustment solution and use of PPE, and set up of the dialysis machine. Data will be aggregated weekly and reported to the Executive Quality Council weekly until 2 months of compliance is sustained. When 100% compliance is sustained for 2 months the monitoring will continue on an ongoing basis monthly. The findings are reported bi-monthly to the Infection Control Committee. Results will be reported quarterly to the Quality Oversight Committee, Medical Executive Committee and the Quality Committee of the Board of Trustees. | | | A 000 | | | |
| A 043 | <p>The following Conditions of Participation were determined to be out of compliance:</p> <p>CFR 482.12 Governing Body CFR 482.13 Patient Rights CFR 482.21 QAPI CFR 482.28 Food and Dietetics CFR 483.41 Physical Environment CFR 482.42 Infection Control</p> <p>GOVERNING BODY CFR(s): 482.12</p> <p>There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible</p> | | | A 043 | | | |

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| A 043 | <p>Continued From page 20</p> <p>for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ...</p> <p>This CONDITION is not met as evidenced by: Based upon observation, record review, and interview, the Governing Body failed to:</p> <p>A.) Protect the patient's right to make informed decisions on their care in 2 (Patient #59 and #227) of 16 surgical patients reviewed. The facility failed to ensure that patients or their representatives were provided with risks and benefits prior to surgical procedures performed. Also, the facility failed to follow their own policy and procedures on Informed consent.</p> <p>B.) Identify the name of the anesthesiologist in the Patient Disclosure and Consent for Surgical Procedure.</p> <p>C.) Ensure that informed consent had been completed and documented for 2 of 2 patients (Patient #56 and Patient #57) observed in the outpatient infusion center (Kirby Glen).</p> <p>Refer to Tag A 0131</p> <p>D.) Follow the dialysis machine's Manufacturer's Direction for Use and the Facility's Policy and Procedure, to ensure air detectors (optical detection mechanism) was engaged during self-testing of a hemodialysis machine, prior to initiation of a patient's hemodialysis treatment, in 1 of 1 hemodialysis machine observed during self- testing. The clamp/optical detection</p> | A 043 | | | |

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| A 043 | <p>Continued From page 21</p> <p>mechanism was not engaged during pre-testing safety tests, puts all hemodialysis patients who receive hemodialysis treatment in the facility at risk of air getting into patients' blood stream during hemodialysis treatment, which can result in actual harm to patients. Hemodialysis Machine #26.</p> <p>E.) Implement the facility's policy and procedure of weighing patients' pre-hemodialysis treatment and post-hemodialysis treatment, during hemodialysis of patients in 2 of 3 hemodialysis Patient's clinical records reviewed. Patient #s 133 and 153.</p> <p>F.) Ensure nursing interventions were put in place to prevent the risk of falls for 2 of 9 patients reviewed.</p> <p>G.) Ensure pediatric crash cart had operable emergency equipment.</p> <p>H.) Recognize chemical restraints/emergency behavioral medications (EBM) as restraints and prohibit the use of "as needed" (PRN) psychotropic medications for the use of restraint or seclusion found in 3 (113, 121, and 117) of 3 patient charts reviewed.</p> <p>I.) Ensure Quality Assurance Performance Improvement (QAPI) followed, tracked, or analyzed data on the usage of violent vs non-violent restraints including chemical restraints or the effectiveness of psychotropic</p> | A 043 | | | |

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| A 043 | <p>Continued From page 22</p> <p>medications in 648 patients listed on the restraint log from 12/18 to 3/19.</p> <p>J.) Ensure policy and procedure offered a scope, scale, or standards for degrees of agitation or aggression. The nurses made a medical judgment to administer a psychotropic medication subjectively without physician oversight.</p> <p>K.) Follow the policy and procedure for Restraint and Seclusion. Nursing staff failed to document patient's need for the medication, actions performed to de-escalate or meet the patients' needs before a psychotropic medication administration, effects of the medication, nursing reassessment, vital signs documented after the medication administration or a face to face in 3 (113, 121, and 117) of 3 charts reviewed.</p> <p>Refer to Tag A 0144</p> <p>L.) Ensure mechanisms were in place and implemented to prevent potential abuse in all patients. The facility failed to screen two (2) of ten (10) employees reviewed to ensure they did not have a background history that indicated criminal, neglect, or abuse charges.</p> <p>Refer to Tag A 0145</p> <p>M.) Ensure a patient's rights to be free from restraints or seclusion when 9 of 9 (Patients #227, #148, #138, #134, #137, #82, #135, #153,</p> | A 043 | | | |

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| A 043 | <p>Continued From page 23</p> <p>and #60) patients were being restrained by the use of four side rails being placed in an upright position without a documented reason. This practice places the patients at risk of entrapment in the rails and or injury from exiting over the top of the side rails.</p> <p>Refer to Tag A 0161</p> <p>N.) Ensure the Performance Improvement committee (PIC) who had the responsibility of coordinating, implementing, and monitoring Performance improvement (PI) was effective.</p> <p>O.) Ensure PI's that were currently in place were being tracked and trended.</p> <p>P.) Ensure high risk and problem-prone areas were focused on in dietary services, contracted services, infection control, surgery services, and pharmacy services.</p> <p>Refer to A 0283</p> <p>Q.) Ensure the staff followed safe food handling practices for the handling of foods, maintain safe temperature for storage of food, dairy products that reached a temperature of 48 degrees Fahrenheit not available for use, and to ensure the repair and maintenance of the kitchen's equipment.</p> <p>R.) Ensure that the facility's two large mechanical dish washers, which were building up copious</p> | A 043 | | | |

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| A 043 | <p>Continued From page 24</p> <p>amounts of steam that was condensing and dripping off the dirty ceiling tiles onto the cleaned dishware, were repaired timely and that the contaminated dishware were not utilized.</p> <p>S.) Ensure the facility had a preventative action plan for the kitchen's sewer drains that had been repeatedly backing up throughout the kitchen food preparation areas creating an unsanitary environment.</p> <p>T.) Ensure the kitchen staff followed safe food handling practices to prevent the use of equipment and dishware that had not been properly cleaned, repaired or were in need of replacement.</p> <p>Refer to A 0619</p> <p>U.) Maintain a safe physical environment when it failed to provide a sustainable correction for the kitchen's sewage drains that had been routinely backing up into the patient food production areas, placing patients at risk of consuming contaminated foods that could result in diarrhea, vomiting, and severe abdominal pain.</p> <p>V..) Ensure that ongoing maintenance inspections to identify areas in need of repair were conducted throughout the overall hospital environment. This failure resulted in environmental rounds not being conducted in 7 of 7 months (September 2018 through March 2019).</p> | A 043 | | | |

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| A 043 | <p>Continued From page 25</p> <p>W.) Have a secure power strip for the use on movable equipment in 1 of 1 Cath Lab procedure rooms. OR 6 and OR 11 (Fannin location) also had electrical extension/adapters with exposed wires plugged into the outlet. The facility also failed to monitor the temperature of the blanket warmer to reduce the risk of thermal burns.</p> <p>Refer to A0701</p> <p>X.) Ensure that equipment was stored/maintained in a manner that prevented potential contamination with cytotoxic drugs (compounds used to destroy cancer cells during chemotherapy) along with developing appropriate processes for cleaning equipment after contamination; and failed to ensure that departments only ordered the appropriate spill kits for cleaning cytotoxic spills in 1 (Kirby Glen Outpatient area) of 2 areas toured that administered chemotherapy.</p> <p>Refer to A0724</p> <p>Y.) Ensure nursing staff practiced nationally recognized standards of practice for infection control by appropriately applying and/or removing Personal Protective Equipment (PPE) when working in isolation rooms, disinfecting mobile computer carts (WOW) and portable equipment, as well as provided patient and family education regarding isolation precautions.</p> <p>Z.) Ensure that staff disinfected transvaginal</p> | A 043 | | | |

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| A 043 | <p>Continued From page 26</p> <p>ultrasound transducers between patients and maintained the sterile field in sterile pharmaceutical compounding areas.</p> <p>AA.) Ensure the sterility of the compounding area of the pharmacy.</p> <p>BB.) Ensure procedure rooms and patient rooms were terminally cleaned following use by patients with the likelihood of infectious disease.</p> <p>CC.) Ensure Environmental Services/Housekeeping maintained isolation precautions to prevent cross contamination while conducting housekeeping services.</p> <p>DD.) Ensure staff observed standard precautions during the provision of hemodialysis care.</p> <p>EE.) Ensure that the walk-in refrigerator #68, which contained the milk products used for the patients, maintained adequate temperatures.</p> <p>FF.) Ensure that the facility's two large mechanical dish washers were maintained in good working order. At the time of the survey, the machines were building up copious amounts of steam that was condensing and dripping off the dirty ceiling tiles onto the cleaned dishware, placing the patients at risk of eating off of contaminated dish wares and water was draining from a ceiling tile in the pots and pans dish washing area.</p> <p>GG.) Ensure that the kitchen's sewage drains were maintained in good working order. At the time of the survey, the drains had been routinely backing up into the patient food production areas,</p> | A 043 | | | |

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| A 043 | <p>Continued From page 27</p> <p>placing patients at risk of consuming contaminated foods.</p> <p>HH.) Ensure that pots and pans were clean and stored appropriately. At the time of the survey, dirty pots and pans were stored wet and available for use, molded vegetables were available for use, and the floors and kitchen equipment were coated in dirty grease and old food particulates creating an unsanitary environment.</p> <p>Refer to Tag A0619</p> <p>II.) Ensure that the facility's two large mechanical dish washers were maintained in good working order. At the time of the survey, the machines were building up copious amounts of steam that was condensing and dripping off the dirty ceiling tiles onto the cleaned dishware.</p> <p>JJ.) Ensure that the facility kitchen's sewer drains, which were repeatedly backing up throughout the kitchen food preparation areas, were repaired and maintained properly.</p> <p>KK.) Ensure that the facility knows the Hepatitis B antibody status or administer the immunization for non-immune staff for 3 (#77, #78, and #194) of 10 surgical staff health records reviewed. The facility failed to follow their policy on Hepatitis B monitoring and follow-up guidance. Also, the facility failed to follow the CDC guidelines.</p> <p>LL.) Ensure that the facility know the Tuberculosis status for 1 (#78) of 10 surgical staff health records reviewed. Also, the facility failed to follow</p> | A 043 | | | |

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| A 043 | Continued From page 28 their policy on Tuberculosis monitoring and follow-up guidance. MM.) Ensure that the facility monitors the expiration dates of the Rapicide strips used to check the concentration level of the peri-acetic acid during high level disinfection. The facility also failed to clean or change the filter on the Jun-Air compressor in the endoscope reprocessing room. NN.) Ensure a clean and sanitary environment in the facility-wide Surgical Department. OO.) Ensure a clean and sanitary environment hospital wide and off-site locations. | A 043 | | | |
| A 084 | Refer to Tag A 0749 CONTRACTED SERVICES CFR(s): 482.12(e)(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner. This STANDARD is not met as evidenced by: Based on review of 10 contracts for services and interviews, the Governing Body failed to exercise effective oversight on the contracted services to ensure the quality and safety of services provided. Findings: Review of the "Contracted Services Evaluation Scorecard" showed 4 components of evaluation: Quality, Regulatory Compliance, Service Delivery, and Customer Service. This evaluation is done to | A 084 | | | |

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| A 084 | <p>Continued From page 29</p> <p>all contracted services regardless of the type of contracted service. There are 4 questions under the Quality section of the evaluation:</p> <ol style="list-style-type: none"> 1. Services are provided in accordance with contract performance expectations. 2. Contractor provides reports of performance in a timely manner, as required by the hospital's Quality Management System, i.e., data reports, records, audit. 3. Quality of service comparable to that provided by staff employed by St. Luke's. 4. Documentation performed and provided by contractor is accurate, complete and timely. <p>These generic questions failed to ensure that the services provided were in accordance with nationally accepted standards of practice as it failed to include quality indicators to ensure that services provided promotes the health and safety of patients. The VP of Quality was asked what were the basis of the rating on the evaluation since there are no quality indicators to ensure the quality of services provided. She stated that there are no quality indicators for evaluation for the contracted services in place but she will be working in improving the evaluation system,</p> <p>The contract with Sodexo for the provision of dietary services and rated as consistently meets expectations. The generic evaluation failed to detect the failure of the contractor's leadership oversight over the dietary service. Consequently, the conditions found during the survey were deemed immediate jeopardy to the health and safety of patients.</p> | A 084 | | | |

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| A 084 | Continued From page 30 This hospital has contracts with 503B Compounding facilities and 3 contracts were reviewed. The contractors were evaluated using the same generic "Contracted Services Evaluation Scorecard." There are no quality indicators to ensure that the 503B Compounding facility meets the Current Good Manufacturing Practices for compounding medication, no provision for an onsite inspection to ensure that the nationally accepted standards for compounding are followed particularly the maintainance of an sterile environment for compounding, following nationally accepted standards for infection control, labeling and storage of compounded drugs. The evaluation score card for the three 503B Compounding facility were rated as consistently meets expectations. The pharmacist in charge of compounded drugs was asked what were the basis for the rating since there are no quality indicators to truly evaluate the quality of serives provided and no onsite nspections were done. The pharmacist stated that the rating was based on the reports provided by the contractors. | A 084 | | | |
| A 115 | PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based upon observation, record review, and interview, the facility failed to: A.) Protect the patient's right to make informed decisions in 2 (Patient #59 and #227) of 16 surgical patients reviewed. The facility failed to | A 115 | | | |

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| A 115 | <p>Continued From page 31</p> <p>ensure that patients or their representatives were provided with risks and benefits prior to surgical procedures performed. Also, the facility failed to follow their own policy and procedures on Informed consent.</p> <p>B.) Identify the name of the anesthesiologist in the Patient Disclosure and Consent for Surgical Procedure.</p> <p>C.) Ensure that informed consent was completed and documented for 2 of 2 patients (Patient #56 and Patient #57) observed in the outpatient infusion center (Kirby Glen)</p> <p>Refer to Tag A 0131</p> <p>D.) Follow Manufacturer's Direction for Use of the dialysis machine and the Facility's Policy and Procedure, to ensure air detectors (optical detection mechanism) was engaged during self-testing of a hemodialysis machine, prior to initiation of a patient's hemodialysis treatment, in 1 of 1 hemodialysis machine observed during self- testing. The clamp/ optical detection mechanism not engaged during pre-testing safety tests, puts all hemodialysis patients who receive hemodialysis treatment in the facility at risk of air getting into patients' blood stream during hemodialysis treatment, which can result in actual harm to patients. Hemodialysis Machine #26.</p> <p>E.) Implement the facility's policy and procedure of weighing patients' pre-hemodialysis treatment and post-hemodialysis treatment, during hemodialysis of patients in 2 (Patient #s 133 and 153) of 3 hemodialysis Patient's clinical records reviewed.</p> | A 115 | | | |

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| A 115 | <p>Continued From page 32</p> <p>F.) Ensure nursing interventions were put in place to prevent the risk of falls for 2 of 9 patients reviewed.</p> <p>G.) Ensure pediatric crash cart had operable emergency equipment.</p> <p>H.) Recognize chemical restraints/emergency behavioral medications (EBM) as restraints and prohibit the use of "as needed" (PRN) psychotropic medications for the use of restraint or seclusion found in 3 (113, 121, and 117) of 3 patient charts reviewed.</p> <p>I.) Ensure Quality Assurance Performance Improvement (QAPI) followed, tracked, or analyzed data on the usage of violent vs. non-violent restraints including chemical restraints or the effectiveness of psychotropic medications in 648 patients listed on the restraint log from 12/18 to 3/19.</p> <p>J.) Ensure policy and procedure offered a scope, scale, or standards for degrees of agitation or aggression. The nurses made medical judgment to administer a psychotropic medication subjectively without physician oversight.</p> <p>K.) Follow the policy and procedure Restraint and Seclusion. Nursing failed to document patient's need for the medication, actions performed to de-escalate or meet the patients' needs before a psychotropic medication administration, effects of the medication, nursing reassessment, vital signs documented after the medication administration or a face to face in 3 (113, 121, and 117) of 3 charts reviewed.</p> | A 115 | | | |

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| A 115 | Continued From page 33 Refer to Tag A 0144 L.) Ensure mechanisms were in place and implemented to prevent potential abuse in all patients. The facility failed to screen two (2) of ten (10) employees reviewed to ensure they did not have a background history that indicated criminal, neglect, or abuse charges. Refer to Tag A 0145 M.) Ensure a patient's rights to be free from restraints or seclusion when 9 of 9 patients were being restrained by the use of four side rails being placed in an upright position without a documented reason. This practice places the patients at risk of entrapment in the rails and/or injury from exiting over the top of the side rails. (Patients #227, #148, #138, #134, #137, #82, #135, #153, and #60) | A 115 | | | |
| A 131 | Refer to Tag A 0161 PATIENT RIGHTS: INFORMED CONSENT CFR(s): 482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. | A 131 | | | |

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| A 131 | <p>Continued From page 34</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to</p> <p>A.) Protect the patient's right to make informed decisions in 2 (Patient #59 and #227) of 16 surgical patients reviewed. The facility failed to ensure that patients or their representatives were provided with the risks and benefits prior to surgical procedures performed. Also, the facility failed to follow their own policy and procedures on Informed consent.</p> <p>B.) Identify the name of the anesthesiologist in the Patient Disclosure and Consent for Surgical Procedure.</p> <p>C.) Ensure that informed consent had been completed and documented for 2 of 2 patients (Patient #56 and Patient #57) observed in the outpatient infusion center (Kirby Glen).</p> <p>This deficient practice had the likelihood to cause harm to all patients receiving surgical and invasive procedures at the facility.</p> <p>Findings:</p> <p>A review of Patient #59's record revealed:</p> <p>There was a facility document titled, "Disclosure and Consent -Anesthesia and/or Perioperative Pain Management (Analgesia)." The consent listed, "General Anesthesia, Deep, and Moderate" as the procedure. There was a patient signature signed by the patient on 3/26/2019 at 2315 (11:15 PM). The Anesthesia signature line was blank. There was no further documentation in the chart</p> | A 131 | | | |

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| A 131 | <p>Continued From page 35</p> <p>to indicate that Anesthesia explained the risks and benefits of the procedure to the patient or their representative. The consent had been witnessed by a registered nurse the day before the procedure and prior to anesthesia discussing the type of anesthesia the patient would receive.</p> <p>A review of Patient #227's record revealed:</p> <p>There was a facility document titled, "Disclosure and Consent Medical and Surgical Procedures". The consent listed, "Colonoscopy with anesthesia, interventions" as the procedure. The physician signature line was signed 3/27 11:35 PM. The Physician signature to the update history and physical indicated the update was completed 11.5 hours after the procedure was started. Also, further review of the time showed there was a mark over the 12:35. The 2 was marked over with a (1) to make the time a 11:35 and the PM was circled to indicate evening time. The patient was in the procedure room at 11:50 AM and procedure started at 12:00 noon.</p> <p>A review of the facility policy titled, "Disclosure and Consent for Medical and Surgical Procedures (Informed Consent) (System)" effective date May 2018 revealed the following:</p> <p>"D. The attending practitioner, the practitioner providing the medical treatment or performing the surgical procedure, including transfusion of blood and blood components, the practitioner's associate, or a practitioner under the Responsible Practitioner's supervision is responsible for discussing the process of and obtaining Informed Consent from the patient or his/her Surrogate Decision Maker.</p> | A 131 | | | |

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| A 131 | <p>Continued From page 36</p> <p>PROCEDURES</p> <p>1. Requirements for Disclosure and Consent Informed Consent is one type of informed decision that a patient or his/her Surrogate Decision Maker may need to make with respect to a medical treatment or surgical procedure related to his/her plan of care. a. In order for the patient or his/her Surrogate Decision Maker to make an informed decision, it is necessary to provide adequate information about the planned medical treatment or surgical procedure in a manner that he/she can understand.</p> <p>b. Written Informed Consent from the patient or his/her Surrogate Decision Maker is required for medical treatments and surgical procedures as indicated below except in medical emergencies.</p> <p>e. Anesthesia and Analgesia i. Types of Anesthesia and Analgesia are listed as either List A or List B Procedures.</p> <p>ii. Refer to section 1.c.v for List A Procedures and section 1.d. iii for List B Procedures.</p> <p>iii. If a treatment or procedure involves Anesthesia or Analgesia, the "Disclosure and Consent - Anesthesia and/or Perioperative Pain Management (Analgesia)" must be used in addition to the appropriate Disclosure and Consent form listed above for medical treatments and surgical procedures, hysterectomy or radiation therapy.</p> <p>Discussion for Informed Consent a. Medical Treatments or Surgical Procedures</p> | A 131 | | | |

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| A 131 | <p>Continued From page 37</p> <p>The attending practitioner, the practitioner performing the treatment or procedure, the practitioner's associate, or a practitioner under the Responsible Practitioner's supervision conducts the Informed Consent discussion with the patient or his/her Surrogate Decision Maker.</p> <p>b. Anesthesia and/or Analgesia</p> <p>An Anesthesia provider and/or the Operating practitioner administering the Anesthesia and/or Analgesia conducts the Informed Consent discussion with the patient or his/her Surrogate Decision Maker. Non-physician health care providers, such as a Certified Registered Nurse Anesthetist (CRNA) or an Anesthesiologist Assistant (AA), are also qualified to conduct the Informed Consent process for Anesthesia and/or Analgesia if they are credentialed and privileged to administer Anesthesia.</p> <p>c. The Informed Consent responsibility may not be delegated to members of the nursing staff or other members of the hospital's workforce.</p> <p>d. Verify that the consent form is completed and patient or his/her Surrogate Decision Maker signed the Informed Consent form prior to commencing the medical treatment or surgical procedure.</p> <p>e. Sign, with date and time, the statement on the consent form that the medical treatment or surgical procedure including the risks, benefits and alternative were explained to the patient or his/her surrogate Decision Maker prior to commencing the medical treatment or surgical procedure. Etc."</p> | A 131 | | | |

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| A 131 | <p>Continued From page 38</p> <p>An interview with Staff RN #8 on 3/27/2019 after 1:00 PM confirmed the above findings.</p> <p>Patient #228 was admitted to the hospital on 03/08/2019 with a diagnosis that included Acute Chronic Stage D Congestive Heart Failure. The patient was admitted and placed in the organ transplant list awaiting a heart.</p> <p>A patient record review conducted on 04/03/2019 revealed that the patient had an Orthotopic Heart Transplant on 03/30/2019. Patient Disclosure and Consent for Surgical Procedure was signed by the patient and Cardiology Surgeon on 03/29/2019 at 6:06 PM.</p> <p>Record review of Patient #228 revealed that on 03/30/2019 at 4:40 AM, a Disclosure and Consent for Anesthesia and Perioperative Pain Management (Anesthesia) was signed by the patient and the anesthesiologist who consented the patient. The anesthesia consent did not have the name of the anesthesiologist who was going to be administering the anesthesia during surgery. Page 7/7 of the anesthesia consent indicated that the anesthesia was administered by "BSL Anesthesiology Group".</p> <p>On 04/03/2019 at 11:15 AM, an interview was conducted with the Cardiac Chief of Anesthesia MD #192. During the interview, the MD stated that the Anesthesia Group has about 19 to 20 anesthesiologists assigned to his department and they cannot predict which one will administer the anesthesia.</p> <p>On the morning of 3-27-2019, patient care in the</p> | A 131 | | | |

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| A 131 | <p>Continued From page 39</p> <p>outpatient infusion area (Kirby Glen) was observed.</p> <p>Patient #56 was to receive chemotherapy treatment. Patient #57 was to receive Intravenous Immunoglobulin (IVIG - a blood product given for the treatment of a number of health conditions). Both treatments require the physician to explain the risks and benefits of the treatments and document that informed consent was obtained. Nursing staff may witness the patient's signature for informed consent after the physician has explained the treatment.</p> <p>Review of Medical Staff Rules and Regulations, Section 4.0 General Conduct of Care; 4.1. Consents; 4.1.2. Responsibility of Member; 4.1.2.3 stated:</p> <p>"Any request of the Member for the nursing staff to obtain a patient's signature for authorization for treatment shall be communicated as an order, signed by the Member, and include any information which is to be inserted or included on the form. Such order does not relieve the Member from the obligation to provide informed consent."</p> <p>Review of the Policy and Procedure Title: Disclosure and Consent for Medical and Surgical Procedures (Informed Consent) (System), Effective Date: May 2018, page 16, item 12, stated:</p> <p>"Filing Consent Form in the Medical Record</p> <p>a. When the consent form is complete and signed by the patient and others, as applicable, place the consent form in the patient's medical record prior to conducting the treatment or procedure that</p> | A 131 | | | |

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| A 131 | <p>Continued From page 40 required Informed Consent.</p> <p>b. Prior to the treatment or procedure, obtain the signature, date and time of the practitioner who discussed the proposed treatment or procedure with the patient or his/her Surrogate Decision Maker.</p> <p>c. A facsimile or copy of a consent form that was signed by the patient or his/her Surrogate Decision Maker while in the physician's private office is acceptable and will be treated as if it were an original copy of the consent form provided the patient or his/her Surrogate Decision Maker verbally verify:</p> <p>i. The signature of the patient or his/her Surrogate Decision Maker; and</p> <p>ii. The authenticity of the consent form on the day of the medical treatment or surgical procedure."</p> <p>RN #113 was observed initiating care for Patient #56 and Patient #57, and interviewed. RN #113 showed a copy of a consent for Patient #56's treatment that had been signed by herself and the patient. RN #113 was asked where the physician signed, as there was no block for a physician's signature. RN #113 explained that the physician consents the patient while in the private office. Once the patient arrives at the outpatient infusion area, the RN verifies with the patient that the physician explained the treatment and then has the patient sign the consent.</p> <p>Prior to initiation of care for Patient #57, the patient was interviewed by the surveyor. Patient #57 was asked if the physician had explained the</p> | A 131 | | | |

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| A 131 | <p>Continued From page 41</p> <p>treatment. Patient #57 stated, "No. He just said I needed to have this done to help my immune system." RN #113 was advised that the patient was claiming the physician had not explained to her about the treatment.</p> <p>RN #113 began to prepare the consent on the computer. When choices for Blood Products were displayed on the computer, RN #113 was asked if the box for IVIG would be checked. RN #113 stated no. RN #113 explained that she was consenting the patient to receive all blood products and that the consent would be good for a year. That way, if the patient had to go to the Emergency Room or if the physician added additional blood products during the course of treatment, a consent would be on file. RN #113 printed a consent for "Transfusion of blood or blood products (components of blood including plasma, platelets, red blood cells, fibrinogen, or others) are provided to increase the amount of these blood products in your blood stream when they are below a reasonable level for your health." The consent did not contain information about the patient's diagnosis of "D81.9 Combined Immunodeficiency" as listed on the patient orders.</p> <p>As the nurse started reading information contained on the consent, the patient stated, "I can't have blood. That's why I'm here. I had a bad transfusion a long time ago and that's why I have all these problems." RN #113 told the patient, "What I'm giving you today doesn't have blood in it so you'll be OK." RN #113 continued with the consent process and allowed the patient to review the orders that had been written by the physician. The patient, after looking at the orders, asked, "You mean I have to come here every month for</p> | A 131 | | | |

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| A 131 | <p>Continued From page 42</p> <p>the next year?" The nurse replied, "I'm sorry I'm the one who had to tell you." The nurse completed the consent process and had the patient sign the consent for all blood products.</p> <p>After leaving the patient area, the nurse was asked if she was going to initiate the IVIG infusion at that time. RN #113 stated that she would initiate the treatment after placing Intravenous (IV) access and obtaining blood specimens to be sent off for the ordered labs. This was despite no physician signed consent, the patient stating the physician had not discussed the medications and her treatment with her, her confusion about the course of her treatment being every 4 weeks for one year, and objection to being consented for blood and all blood products due to a previous bad transfusion.</p> <p>On the afternoon of 4-3-2019 at 1:30 PM, a meeting was conducted with hospital leadership concerning the physician's signature on consents. Staff #37 presented informed consent audit data for December 2018 and January through March 2019. The consent problem had been identified by Nursing and was being tracked. The physician's statement of consent and electronic signature was on the order that was placed for nursing to verify consent with the patient. When the physician placed the electronic order, the physician was certifying that he/she had discussed the treatment or procedure with the patient.</p> <p>During the survey, it was discovered that there was no electronic order for the nurse to verify consent placed by the physician when ordering treatment in the outpatient setting. Therefore, there was no documentation of the physician</p> | A 131 | | | |

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| A 131 | Continued From page 43 | A 131 | | | |
| A 144 | <p>PATIENT RIGHTS: CARE IN SAFE SETTING CFR(s): 482.13(c)(2)</p> <p>The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility's Registered Nurse failed to:</p> <p>A.) Follow Manufacturer's Direction for Use of dialysis machine and the Facility's Policy and Procedure, to ensure air detectors (optical detection mechanism) was engaged during self-testing of a hemodialysis machine, prior to initiation of a patient's hemodialysis treatment, in 1 of 1 hemodialysis machine observed during self- testing. The clamp/optical detection mechanism not engaged during pre-testing safety tests, puts all hemodialysis patients who receive hemodialysis treatment in the facility at risk of air getting into patients' blood stream during hemodialysis treatment, which can result in actual harm to patients. Hemodialysis Machine #26.</p> <p>B.) Implement the facility's policy and procedure of weighing patients pre-hemodialysis treatment and post-hemodialysis treatment, during hemodialysis of patients in 2 (Patient #s 133 and 153) of 3 hemodialysis Patient's clinical records reviewed.</p> <p>C.) Ensure nursing interventions were put in place to prevent the risk of falls for 2 of 9 patients reviewed.</p> <p>D.) Ensure pediatric crash cart had operable</p> | A 144 | | | |

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| A 144 | <p>Continued From page 44 emergency equipment.</p> <p>E.) Recognize chemical restraints/emergency behavioral medications (EBM) as restraints and prohibit the use of "as needed" (PRN) psychotropic medications for the use of restraint or seclusion found in 3 (113, 121, and 117) of 3 patient charts reviewed.</p> <p>F.) Ensure Quality Assurance Performance Improvement (QAPI) followed, tracked, or analyzed data on the usage of violent vs. non-violent restraints including chemical restraints or the effectiveness of psychotropic medications in 648 patients listed on the restraint log from 12/18 to 3/19.</p> <p>G.) Ensure policy and procedure offered a scope, scale, or standards for degrees of agitation, or aggression. The nurses made medical judgment to administer a psychotropic medication subjectively without physician oversight.</p> <p>H.) Follow the policy and procedure Restraint and Seclusion. Nursing staff failed to document patient's need for the medication, actions performed to de-escalate or meet the patients' needs before a psychotropic medication administration, effects of the medication, nursing reassessment, vital signs documented after the medication administration or a face to face in 3 (113, 121, and 117) of 3 charts reviewed.</p> <p>Findings:</p> <p>A.) Review of the Manufacture's Direction for Use for Fresenius 2000 K hemodialysis machine, Page 49 directs users as follows: "Standard Prime method: Warning the tubing beneath the</p> | A 144 | | | |

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| A 144 | <p>Continued From page 45</p> <p>venous drip chamber must be inserted in the venous line clamp and optical detection."</p> <p>Review of the Facility's current Policy and Procedure on Hemodialysis Treatment, effective February 2019 directed staff as follows: "The setup of the machine will be according to manufacturer's guidelines."</p> <p>Observation on 04/01/2019 at 9:15 a.m., revealed Registered Nurse (#169) was observed on the facility's hemodialysis unit in room #6, at Patient #133's bedside.</p> <p>The Patient was lying on a (stretcher) and the Registered Nurse was preparing to initiate hemodialysis treatment on the Patient. The Patient told the Registered Nurse. "Make sure you set the timer for my saline because they forget and then I clot."</p> <p>Observation of the room revealed a Fresenius 2008K hemodialysis machine # 26, set up with external blood lines and dialyzer. Observation revealed the pre- tested safety tests were completed and the hemodialysis machine was ready to initiate hemodialysis treatment on the patient.</p> <p>Observation of the hemodialysis machine revealed, the external blood line tubing was not inserted into the venous line clamp and optical detector.</p> <p>Interview with Registered Nurse (#169), she stated, the hemodialysis machine was pre-tested and ready to initiate hemodialysis treatment on the Patient but she was going to do central</p> | A 144 | | | |

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| A 144 | <p>Continued From page 46</p> <p>venous catheter care on the Patient. This central venous catheter is the line used during hemodialysis of the Patient.</p> <p>The Surveyor immediately notified Registered Nurse (#169) and the (Dialysis Unit's Director) that the external blood line was not inserted in the venous line clamp and optical detector during pre-testing of the hemodialysis machine.</p> <p>Registered Nurse (#169) stated "I will retest the machine."</p> <p>Subsequent interview on 04/01/2019 at 9:45 a.m., with Registered Nurse (#169), she stated; "My apology, I should have engaged the air detector prior during pre-testing of the hemodialysis machine. This could harm my patient. "</p> <p>Interview on 04/01/2019 at 9:25 a.m., with Patient #133 revealed the staff sometime forgets to give his Normal Saline flushes and so he asked the nurse to set the clock so that his Heparin could be administered to him.</p> <p>Failure of the Registered Nurse to follow the Manufacture's Direction for Use puts the patient at risk for air entering his blood stream during hemodialysis of the patient. This failed practice has the potential to affect all patients receiving hemodialysis treatment in the facility.</p> <p>This deficient practice was determined to pose an Immediate Jeopardy to patient health and safety, and placed all patients receiving dialysis at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>B. WEIGHTS</p> | A 144 | | | |

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| A 144 | <p>Continued From page 47</p> <p>Review of the facility's current policy and procedure on Hemodialysis Treatment, revised February 2019, directs staff as follows: "Hemodialysis treatment process by the dialysis nurse: Weigh patient pre and post dialysis. A pre-dialysis nursing assessment of the patient will be performed and documented in the electronic medical record (EMR) or Hemodialysis Documentation Flow sheet during downtime. Take baseline vital signs pre - dialysis."</p> <p>PATIENT (#133)</p> <p>Patient (#133) was observed on 04/02/2019 at 11:20 a.m. in his room on the renal unit. The Patient was alert and oriented to person place, time and situation.</p> <p>Interview on 04/02/2019 at 11:21 a.m., with Patient #133 revealed, the Registered Nurse did not weigh him prior to or after hemodialysis treatment on 04/01/2019.</p> <p>Review of the Patient's clinical record (treatment sheet), revealed documentation which indicated the Patient received hemodialysis treatment in the hospital on 04/01/2019.</p> <p>Review on 04/02/2019 of Patient #133's clinical record (Hemodialysis treatment sheet and nurses' notes revealed no documentation of a pre-treatment or post treatment weight taken on 04/01/2019.</p> <p>Further review of Patient #133's clinical record (treatment sheet), dated 03/29/2019 revealed, the Patient received hemodialysis treatment on 03/29/2019. Review of the Patient's clinical record</p> | A 144 | | | |

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| NAME OF PROVIDER OR SUPPLIER CHI ST LUKE'S HEALTH BAYLOR COLLEGE OF MEDICINE ME | | | STREET ADDRESS, CITY, STATE, ZIP CODE 6720 BERTNER HOUSTON, TX 77030 | | |
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| A 144 | <p>Continued From page 48</p> <p>revealed no documentation of a pre- treatment weight.</p> <p>Patient (#153)</p> <p>Review of the Patient (#153's) clinical record (treatment sheet), dated 03/31/2019, revealed the Patient received hemodialysis treatment on 03/31/2019 in the hospital.</p> <p>Review on 04/02/2019 of Patient (#153) clinical record revealed no documentation of a pre-treatment or post-treatment weight taken on the patient 03/31/2019, during his hemodialysis treatment.</p> <p>The Patients' clinical records were reviewed with the hospital's Charge Nurse for the hemodialysis unit. She confirmed that the Patients pre and post treatment weights were not done during hemodialysis treatment.</p> <p>C.) Review of the facility provided Fall Management - Patient Care (dated March 2019) reflected, "C. High Risk Fall Precautions ... vi. Activate bed alarm/ chair alarm, if the following patient symptoms/signs are present:</p> <ul style="list-style-type: none"> a. Patient is impulsive and/or confused, b. Patient is non-compliant with calling for assistance before getting out of bed, c. Patient has altered mental status, d. Patient overestimates his/her abilities or is forgetful of limitations, | A 144 | | | |

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| A 144 | <p>Continued From page 49</p> <p>e. Place yellow bed alarm sign on the patient's door"</p> <p>An observation on the morning of 4/1/19, at 10:52 am, revealed Patient #82 laying on the floor of his room. A yellow sign was on the door, "High Fall Risk, Bed/Chair/Alarm". Further observation revealed, the Patient's bed alarm was not alarming and all four side rails had been in the upright position. Patient #82 had been admitted on 2/6/19 with a diagnosis of Right sided paralysis, confused, and non-verbal.</p> <p>During an interview on the morning of 4/1/19, Staff #82, Quality confirmed the findings and stated, "He was holding on to the rail, when I lowered it, he went all the way to the floor.... the four side rails were up."</p> <p>During an interview on the morning of 4/1/19, on the inpatient unit, when asked if Patient #82's bed alarm was on Staff #171, stated, "It's off," and confirmed Patient #82's need for the bed alarm due to confusion.</p> <p>An observation on the morning of 4/1/19, in room 215, revealed a yellow sign on Patient #134's door "High Fall Risk, Bed/Chair/Alarm". When asked if the bed alarm was on, Staff #172, stated, "Yes." When asked how you can tell if the alarm is set, Staff #172, determined the alarm was off. Staff #172, attempted to set the alarm two times more. The charge nurse instructed Staff #172, to hold the button down for a few seconds; Staff #172, did as she was instructed, the bed alarm beeped, which indicated the bed was alarmed.</p> | A 144 | | | |

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| A 144 | <p>Continued From page 50</p> <p>During an interview on the morning of 4/2/19, Staff #132, stated, "We need to re-educate the staff on the bed alarms...."</p> <p>During an interview on the morning of 4/2/19, Staff #170, stated, "We found most of our falls are related to toileting ... we placed bedside commodes in the rooms on the towers.... we didn't see as much of a decrease as we wanted.... In October, we did a focus on the falls, we didn't want to wait for the annual training. We have been working on our audit tool, it wasn't standardized, we are planning on rolling it out at the annual training in the coming months."</p> <p>During an interview on the morning of 4/3/19, Staff #170, stated, "... We review the incident reports We found the staff thought they had turned on the bed alarms.... The Hill-Rom representative provided training and information to the different units.... We are in the process of re-educating all the staff."</p> <p>D.) Record review of current facility policy, "Code Blue Response at Baylor St. Luke's Medical Center, Patient Care" dated June 2018, stated the following definition:</p> <p>Broselow Tape/Hinkle Pediatric Emergency Cart - An emergency resuscitation color-coded system that matches equipment and medication doses for the size of the infant or child.</p> <p>Equipment: For patients under the age of 12 or less than 36 kg (kilogram), a Broselow Tape/Hinkle Pediatric Emergency Cart will be available in the patient care area.</p> | A 144 | | | |

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| A 144 | <p>Continued From page 51</p> <p>Observation on 03/29/2019 at 10:10 a.m., at Pearlman Emergency Center revealed the pediatric laryngoscope blades did not fit the laryngoscope handles in the pediatric emergency cart.</p> <p>The pediatric cart was noted to have different laryngoscope handles, (3-Heleflex, 1-Heine) and different blades (3-McIntosh, 2-Miller), so the blades did not fit into the handles which rendered the laryngoscope set unusable in the event of emergency.</p> <p>It was also noted the laryngoscope did not have batteries and was not ready for use.</p> <p>E - H.</p> <p>Review of Patient #113's chart revealed he came into the Emergency Department on 2/25/19. Patient #113 was an 85-year-old male, with a complaint of abdominal pain. Patient #113 was diagnosed with Dementia without behavioral disturbance, Unspecified Dementia type, type 2 Diabetes, Essential Hypertension, and Acute cystitis without hematuria.</p> <p>Review of the ED Physician notes dated 2/25/19, "Physical Exam: Constitutional: He appears well-developed and well nourished. No distress. Neurological: He is alert No cranial deficit."</p> <p>Review of the ED Nurses Notes 2/25/19:</p> <p>2/25/19 12:28PM, "Lower abdominal pain x and is restless. I asked pt if he is having chest pain-he said yes." There was no documentation in how the pain was addressed.</p> | A 144 | | | |

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| A 144 | <p>Continued From page 52</p> <p>2/25/19 at 12:44PM- "Per Pt son at bedside PT has had abdominal pain for the last 2 days. The pain has been intermittent for the last few weeks. Pt has a HX of dementia and several CVAs in the past years. Pt is restless and pulling at heart monitor and BP cuff. Pt is not able to be comfortable in bed." There was no documentation on what the nurse did to alleviate discomfort or restlessness.</p> <p>2/25/19 at 1:36PM Pt refuses to stay in bed and wants to be in wheelchair.</p> <p>2/25/19 at 4:15PM- Pt up out of bed walking in room, per son pt face does not look right "drooping on left side and his speech not right slurred" pt does have history of strokes in past. Pt only complaint of mid abdomen pain and does not feel right>Spoke with ____ (physician) in regards patients son wanting to speak with him about test and what was going on. had informed pt's son of ____ (physician) notified (sic).</p> <p>2/25/19 at 6:02PM- Pt returned from CT.</p> <p>2/25/19 at 7:15PM-Collected urine from pt and sent to lab. Son is upset about the wait and informed him Of why and he was not happy with My answer. Again notified ____ (physician) of pt son being angry .(sic)</p> <p>2/25/19 at 8:18PM-Son angry with ____ (physician) and yelling at him. ____ (physician) had pt son sign discharge and son yelling to speak with supervisor and son kept pushing pt out and complaining of the wait.(sic)"</p> <p>Review of the "ED Provider Notes - ED Notes"</p> | A 144 | | | |

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| A 144 | <p>Continued From page 53</p> <p>revealed a comment documented on 2/25/19 at 12:41PM-</p> <p>"Plan VSS. At mental status baseline per caretaker. Abd benign, +UTI but no pyelo. The patient has been evaluated and is being discharged from the ED. There is no indication for emergent hospitalization or surgery at this time. I have explained to the patient and/or their family in detail their discharge instructions and need for urgent follow up with their Primary Care Doctor and/or Specialist, as not all diagnoses can be ruled out in one ED visit as some disease processes take more time to become apparent. I have discussed and reviewed any diagnostic studies that were performed and need for follow up for notable abnormalities. I have also instructed the patient and/or family to seek immediate medical care if their condition worsens, they do not improve as expected, or they experience any new symptoms. The patient is well-appearing and being discharged in stable condition. RN notes acknowledged, differences noted. All history and physical exam data obtained on date of service."</p> <p>An order for Geodon (psychotropic) 10 mg injection was ordered on 2/25/19 at 1400 (2:00PM). There was no documentation found in the order or physician notes on why the patient was ordered a psychotropic medication. Review of the "All Orders" revealed the injection was given at 1427 (2:27PM). There was a nursing comment that the medication was administered in the "Left Upper". There was no description of what "Left Upper." There was no documentation found of the patients need for the medication, actions performed to de-escalate or meet the patients' needs before a psychotropic medication</p> | A 144 | | | |

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| A 144 | <p>Continued From page 54</p> <p>administration, effects of the medication, nursing reassessment, vital signs documented after the medication administration or a face to face.</p> <p>Review of the policy and procedure Restraint or Seclusion revealed the definition of a "Chemical Restraint - The use of any chemical, including pharmaceuticals, through topical application, oral administration, injection, or other means, for purposes of restraining an individual and which is not a standard treatment for the individual's medical or psychiatric condition. Chemical Restraints are used for the management of violent, self-destructive behavior.</p> <p>Note: A psychoactive medication administered outside of the patient's current medication regimen, used to control the patient's behavior rather than for its therapeutic benefit would be considered a Chemical Restraint. For example, a patient currently taking Drug 1 becomes violent and de-escalation techniques are exhausted. Following assessment, to control the patient's violent behavior the Physician Orders Drug 2. If Drug 2 is not part of the patient's current regimen, or even in the same drug category as Drug 1, this would be considered a Chemical Restraint to control the patient's violent behavior.</p> <p>Note I: The patient has a right to be free of Restraint and also has a right to refuse medications, unless a court has ordered medication treatment. Additionally, in accordance with State law, some patients may be medicated against their will in certain emergency circumstances. Staff is expected to use the least restrictive method of administering the medication to avoid or reduce the use of force, when possible."</p> | A 144 | | | |

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| A 144 | <p>Continued From page 55</p> <p>F. Assessment, Monitoring and Evaluation of the Patient in Violent/Self-Destructive Restraints or Seclusion or Those Receiving Chemical Restraint</p> <p>1. Assessment and monitoring may only be conducted by qualified staff within the individual's scope of clinical practice and State law (e.g., checking vital signs, skin integrity, hydration, assisting with range of motion exercises, etc.):</p> <p>1. Monitoring - Monitoring is performed by physicians or other LIPs or staff who has been trained in accordance with this policy to monitor the condition of patients in Restraint or Seclusion. Qualified staff, other than the RN, may perform monitoring activities and provide for general care needs within scope of practice and job responsibilities.</p> <p>2. Assessment - Shall be conducted by a RN, QLP or LIP.</p> <p>ii. The selection of an intervention and determination of the necessary frequency of assessment and monitoring is individualized, taking into consideration variables such as the patient's condition, cognitive status, and risks associated with the use of the chosen intervention and other relevant factors.</p> <p>iii. For patients in violent/self-destructive Restraints and Seclusion or receiving Chemical Restraint, the following is monitored continuously and documented at least every 15 minutes:</p> <p>1. Respiratory status: 2. Circulation; 3. Nutrition needs: 4. Hydration needs:</p> | A 144 | | | |

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| A 144 | <p>Continued From page 56</p> <p>5. Elimination needs; 6. Level of distress/agitation; 7. Skin integrity 8. Signs of any injury 9. Readiness for discontinuation (is assessed, confirmed and documented by the responsible RN, QLP or LIP): and 10. Response to intervention, rationale for continued use."</p> <p>Patient #121</p> <p>Review of Patient #121's chart revealed she was admitted to the facility on 2/7/19. Patient came to the ED and stated she was suicidal. Patient #121 was admitted due to infected wounds under her breast. Patient #121 had a past medical history of the following:</p> <p>MVA Paraplegic immobility syndrome Neurogenic bladder Hx of AKA (above knee amputation) Chronic Pain Decubitus Ulcer Schizophrenia Osteomyelitis of multiple sites Suicidal ideation Wound abscess</p> <p>Patient #121 had a psychiatric consult as follows: Physician #176 documented on 2/9/19 at 2:44PM PSYCHIATRY CONSULT 2/7/2019 5:40 PM 2/9/2019 2:44 PM</p> <p>IMPRESSION: Bipolar do, r/o schizophrenia. Extremely irritable but redirectable. Agreeable to</p> | A 144 | | | |

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| A 144 | <p>Continued From page 57</p> <p>restart psych meds, declines to provide further history.</p> <p>RECOMMEND: Titrate depakote to 500mg BID Risperidone 2mg qhs Celexa 20mg daily. Geodon 20mg IM prn severe agitation.</p> <p>Note pt usually calms down when left alone. Pt w hx of providing very limited cooperation and poor regard for hospital norms/policies. Any threatening or antisocial behavior should be reported to HPD for processions as the law sees fit. Avoid opiates and benzos unless there is absolute medical necessity for either one. In past admissions, prescription of controlled substance have let to disruptive and counter therapeutic behaviors on this patient. (sic)</p> <p>Continue suicide precautions for now. Hx of secondary gain and intentionally trying to prolong hospitalizations due to homelessness. Will continue to assess for safety.(sic)</p> <p>Thank you for asking us to assist you in this patient's care. Will follow.</p> <p>ID: 31 y.o. female C.C: What do you want? H.P.I.: Pt w hx of schizoaffective bipolar do and polysubst use, decubitus ulcer and paraplegia for over 10, admitted for SI. Pt appears angry and bothered as I walk into the room. Yells at me at times and gets upset when I indicate that behavior is not acceptable, but able to calm down. She tells me she doesn't want to discuss any of her circumstances prior to admission and says that she is just tired of being homeless and paraplegic. Interested in housing. Agreeable to be</p> | A 144 | | | |

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| A 144 | <p>Continued From page 58</p> <p>restarted on psych meds that helped before, I offered the names and she was ok w therm. She then asks for ativan (much disruption about this in the past) and I made it clear we would not be using benzos as part of her treatment. UDS negative for all substances. On chart review she's had people bring her drugs even when hospitalized, but it seems SA part is better controlled now. Pt denies any specific plan to hurt herself, does not want to talk to me any further. Does not appear to respond to AVH right now. Unable to perform 10 point review of systems due to lack of pt cooperation." (sic)</p> <p>Review of the Nurses notes dated 2/11/19 at 10:16PM The house supervisor documented, "Paged to 54579 (patient's room phone). ____ (Patient #121) answered and I introduced myself. ____ (Patient #121) is upset and wanting something to calm her down. I looked at patient's EPIC chart, on the MD sticky note by Dr. ____ (Physician 176) it says to avoid opiates and benzo if possible. Patient started yelling on the phone to me. I listened and explained I would talk with bedside nurse about her request. Talked with Mini (night nurse) and patient has something ordered (patient wanting ativan which is not ordered) and will give to patient. Per bedside nurse patient is yelling in the room for medication."</p> <p>Review of the nurses notes and flow sheets revealed there was no found documentation of the patient's behavior before the house supervisor called the patient. There was no documentation of de-escalation or other comfort measures provided. There were no documented vital signs to see if the patient was in pain, or withdrawal.</p> | A 144 | | | |

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| A 144 | <p>Continued From page 59</p> <p>Review of Patient #121's chart revealed she was ordered Geodon 20mg IM on 2/9/19 prn severe agitation. The medication was administered on 2/11/19 at 2250 (10:50PM) under the nurse's discretion. There was no found documentation that the physician was consulted before administering a psychotropic medication for "yelling".</p> <p>Interview with RN #216 confirmed the above findings. Staff #216 confirmed there was no scope, scale, or standards for degrees of agitation or aggression for a nurse to follow when administering PRN psychotropic medications.</p> <p>Review of the Pfizer medical information insert revealed that there is no specific antidote to Geodon (ziprasidone), and it is not dialyzable. Geodon is NOT to exceed 40 mg a day. If the nurse followed the physician orders and administered Geodon 20mg IM PRN it would add up to 120mg a day. The patient would have received an overdose of 80mgs; twice the daily recommendation. This could have resulted in depressed respirations, hypotension, circulatory collapse and possible death if overdose is not detected.</p> <p>Patient #117</p> <p>Review of Patient #117's chart revealed he was admitted to the facility on 1/4/2019.</p> <p>Patient #117 was ordered "Haldol 5 mg Intravenous every 6 hours PRN Agitation" on 1/7/19 at 1705. Review of the Medication Administration Record (MAR) revealed Patient</p> | A 144 | | | |

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| A 144 | <p>Continued From page 60</p> <p>#117 received an intravenous injection of Haldol 5 mg on 1/08/19 at 0043 (12:43AM) and again by the same nurse on 1/10/19 at 2225 (10:25PM).</p> <p>Review of the nurse's notes "flowsheet" for 1/8/19 revealed there was no documentation of why the patient was given the Haldol or if the Haldol was effective. There was no found documentation that a physician was notified.</p> <p>Review of the nurse's notes "flowsheet" for 1/8/19 revealed Patient #117 was in bilateral wrist restraints when Haldol was administered. There was no documentation noted on the patient's behavior until 2252 (10:52PM) 25 minutes after the medication was administered. The nurse documented "Combative, irritable, and restless." There was no documentation found that MD was aware of Haldol administration at 2225 (10:52PM).</p> <p>An interview was conducted with RN #154 on the morning of 3/28/19. RN #154 reported that he recently had a severely agitated patient in the ED that required an injection of Haldol due to her screaming and yelling but he did not document that as a restraint. RN #154 was not aware that it was a restraint. RN #154 stated, "I thought they had to be violent to be a restraint."</p> <p>An interview was conducted with Staff #37 on 3/28/19 at 8:45AM. Staff #37 provided the surveyor with a restraint log that had non-violent and violent restraints. Out of 648 restraints listed on the log only 2 restraints were listed as violent. There were NO chemical restraints listed. Reported that QAPI committee had realized that the nursing staff are not reporting violent restraints including chemical restraints. Staff #37</p> | A 144 | | | |

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| A 144 | Continued From page 61 reported that QAPI had just started to look into the issue last week but had no plans or process in place. Staff #37 reported that she was aware the process was broken and there was no face to face's being done in the restraint process and it needs to "be worked on." Staff #37 confirmed she was aware the physicians were writing chemical restraint orders as PRN. | A 144 | | | |
| A 145 | PATIENT RIGHTS: FREE FROM ABUSE/HARASSMENT CFR(s): 482.13(c)(3) The patient has the right to be free from all forms of abuse or harassment. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure that mechanisms were in place and implemented to prevent potential abuse to all patients. The facility failed to screen 2 (RN#214 and RN#178) of 10 employees reviewed to ensure they did not have a background history that indicated criminal, neglect, or abuse charges. During review of personnel records the following observations were noted: RN #214 did not have a background history in the personnel file. RN #214 has been employed at the facility since 1981; over thirty-eight years. RN #178 did not have a background history in the personnel file. RN #178 has been employed at the facility since 1991; over 28 years. During an interview with RN #207 and Staff #195 on April 1, 2019, after 8:30 AM, it was revealed | A 145 | | | |

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| A 145 | Continued From page 62 the facility did not currently have a process to screen long term employees. Staff #195 said, the facility screens all newly hired employees and any employee that was promoted. Staff #195 said, the facility had recently discovered the gap in the facility screening processes, specifically relating to long term employees and would be working on that process. RN #207 and Staff #195 confirmed the above findings. Review of the facility policy titled, "Applicant Background Checks Policy" with a revision date of 11/1/2018 revealed the following: "Coverage/Eligibility: Background screenings will be conducted for: ...Current employees under specific circumstances to meet business or regulatory needs ... Human Resources Responsibilities: ...3. Where required by State Law, current employees will also be required to successfully complete updated criminal background check investigations in order to remain employed." | A 145 | | | |
| A 161 | PATIENT RIGHTS: RESTRAINT OR SECLUSION CFR(s): 482.13(e)(1)(i)(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or | A 161 | | | |

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| A 161 | <p>Continued From page 63</p> <p>other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort)</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure a patient's rights to be free from restraints or seclusion when 9 (Patients #227, #148, #138, #134, #137, #82, #135, #153 and #60) of 9 patients were being restrained by the use of four side rails being placed in an upright position without a documented reason. This practice places the patients at risk of intrapment in the rails and or injury from exiting over the top of the side rails.</p> <p>Findings:</p> <p>Review of the facility provided policy Restraint or Seclusion (dated March 2019) reflected, " ... St. Luke's uses Restraint only to provide for the immediate physical safety of the patient ... measures taken to protect the patient from falling out of bed... Note: Raising all four side rails in order to restrain a patient (as this may immobilize or reduce the ability of a patient to move his or her arms legs, body, or head freely) to ensure the immediate physical safety of the patient is considered a Restraint and is not exempt from policy requirements"</p> <p>Observations made on the morning of 4/1/19, on the inpatient units, revealed Patients #134, #137, #82, #135, and #60 were lying in bed with four side rails up. The patient's medical records do</p> | A 161 | | | |

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| A 161 | <p>Continued From page 64</p> <p>not reflect physicians' orders for the restraints or that the restraints were not in place for positioning.</p> <p>During an interview on the morning of 4/1/19, on the in-patient unit, Staff #170 confirmed four side-rails would be considered a restraint.</p> <p>During an interview on the morning of 4/2/19, in an administrative conference room, Staff #180, stated, "I do audits on all restraints Most of the restraints are on the ICU ... I do the audits weekly." When asked if Staff #180 observes the units for unordered restraint use, Staff #180 stated, "I am only reviewing the medical records." When informed of the numerous patients with four side rails up, Staff #180 stated, "Four side rails is a restraint."</p> <p>Patient #227</p> <p>Interview on 04/03/2019 at 8:54 a.m., with Registered Nurse #183 revealed, Patient #227 was bedbound, confused with history of dementia, oriented to self, and has to be turned and repositioned.</p> <p>On 04/03/2019 at 9:00 a.m., revealed, Patient #227 was observed in her room on the 9th floor. The Patient was lying in bed with 4 side rails up. The Patient had a yellow fall risk armband in place to her right arm. The bed alarm was activated and the bed was maintained the lowest level.</p> <p>Interview on 04/03/2019 at 9:50 a.m., with the Unit's Nurse Manager revealed, Patient #227 does not have an order for restraint and should</p> | A 161 | | | |

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| A 161 | <p>Continued From page 65 not have all 4 side rails up.</p> <p>Interview on 04/03/2019 at 9:55 a.m., with Registered Nurse #183 who was assigned to the Patient revealed, the 4 side rails were put in place by the night shift staff.</p> <p>Patient #153</p> <p>Interview on 04/03/19 at 9:15 a.m., with Registered Nurse #182 revealed, the Patient was previously in the medical intensive care unit with altered mental status but is now alert and oriented X 4.</p> <p>On 04/03/2019 at 9:20 a.m., Patient #153 was observed in his room with 4 side rails up. The Patient was eating his breakfast unaccompanied. The Patient was alert and oriented to person, place , time, and situation. He was contracted in his upper extremities but was able to feed himself independently.</p> <p>Interview on 04/03/2019 at 9:16 a.m., with Registered Nurse #182 stated, the Patient is not a fall risk because the Patient is contracted and he has 4 side rails up.</p> <p>Interview on 04/03/2019 at 9:45 a.m., the Unit's Nurse Manager stated, the Patient does not have a physician's order for restraint and so the four side rails of the bed should not be up.</p> <p>Review of the Patient's Comprehensive Care Plan, dated 03/26/2019 revealed the following documentation, Problem:" Safety ensure armband on, uncluttered walking paths in room, adequate room lighting, call light and overbed</p> | A 161 | | | |

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| A 161 | Continued From page 66 table within reach, bed in low position, wheels locked, side rails up per policy and non- skid footwear provided." | A 161 | | | |
| A 263 | Review of the Facility's Current Policy and Procedure on Restraint or seclusion revised March 2019 direct staff as follows: "Measures taken to protect the patient from falling out of bed (side rails during anesthesia recovery, during stretcher transport, when sedated, when experiencing involuntary movement, or on certain therapeutic beds). Note: Raising all four side rails in order to restrain a patient, (as this may immobilize or reduce the ability of a patient to move his or her arms, legs, body, or head freely) to ensure the immediate physical safety of the patient is considered a Restraint and is not exempt from policy requirement. " QAPI CFR(s): 482.21 The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. | A 263 | | | |

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| A 263 | Continued From page 67 This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure data collected was used to identify opportunities for improvement. The facility failed to track and measure success on performance improvement projects for the timeframe of December 2018 - February 2019. The facility failed to: A. Ensure the Performance Improvement committee (PIC) who had the responsibility of coordinating, implementing, and monitoring Performance improvement (PI) was functional. B. Ensure PI's that were currently in place were being tracked and trended. C. Ensure high risk and problem-prone areas were focused on in dietary services, contracted services, infection control, surgery services and pharmacy services. D. Follow the Life Safety Management/EOC Plan as evidenced by findings on Environment of Care rounds were not tracked and trended. Data from EOC rounds was gathered and reported but no Performance Improvement resulted from that data. Refer to A 0283 | A 263 | | | |
| A 283 | QUALITY IMPROVEMENT ACTIVITIES CFR(s): 482.21(b)(2)(ii), (c)(1), (c)(3) (b) Program Data (2) [The hospital must use the data collected to -] (ii) Identify opportunities for improvement and | A 283 | | | |

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| A 283 | <p>Continued From page 68 changes that will lead to improvement.</p> <p>(c) Program Activities (1) The hospital must set priorities for its performance improvement activities that-- (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care.</p> <p>(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure data collected was used to identify opportunities for improvement. The facility failed to track and measure success on performance improvement projects for the timeframe of December 2018 - February 2019. The facility failed to:</p> <p>A. Ensure the Performance Improvement committee (PIC) who had the responsibility of coordinating, implementing, and monitoring Performance improvement (PI) was functional.</p> <p>B. Ensure PI's that were currently in place were being tracked and trended.</p> <p>C. Ensure high risk and problem-prone areas were focused on in dietary services, contracted</p> | A 283 | | | |

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| A 283 | <p>Continued From page 69</p> <p>services, infection control, surgery services, and pharmacy services.</p> <p>D. Follow the Life Safety Management/EOC Plan as evidenced by findings on Environment of Care rounds were not tracked and trended. Data from EOC rounds was gathered and reported but no Performance Improvement resulted from that data.</p> <p>This deficient practice had the likelihood to cause harm to all patients.</p> <p>Findings:</p> <p>PERFORMANCE IMPROVEMENT COUNCIL (PIC) AND TIER SYSTEM</p> <p>Review of a facility's "QUALITY MANAGEMENT PROGRAM AND PLAN-COMMITTEE REPORTING STRUCTURE" dated December 2018 revealed the following:</p> <p>The Performance Improvement Council (PIC) was listed on the organization chart in a manner where not all department's information flowed through them. According to the chart the PIC functions were to coordinate, implement, and monitor PI priorities and activities using an interdisciplinary collaborative approach throughout the organization.</p> <p>During an interview on 03/25/2019 after 9:34 a.m., Quality Staff #37 and #130 reported that the PIC portion of the quality was stopped December 2018 and would start back in April 2019. They did not understand why the last administration stopped it.</p> | A 283 | | | |

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| A 283 | <p>Continued From page 70</p> <p>They revealed the following three non-formal quality tracks had been recently developed to help escalate concerns up to administration. They were:</p> <p>Tier 1- Direct care staff daily huddles in each department where they talked about Performance improvements (PI).</p> <p>Tier 2- Hospital leaders who met daily to discuss concerns, determine if education was needed and if policy changes were needed.</p> <p>Tier 3- Senior leadership who met daily at 11:30 a.m. They looked at quality measures, hospital throughput, staffing, and CMS readiness.</p> <p>Quality Staff #37 and #130 stated, there were no meeting minutes being kept at these meetings. At the Tier 2 level the information was put on spread sheets. The information was being tracked, but no trending was being done.</p> <p>During an interview on 03/29/2019 after 10:00 a.m., Quality Staff #130 confirmed they were not tracking all the PI's on the huddle boards for the Tier I level.</p> <p>DIETARY PERFORMANCE IMPROVEMENT PROJECTS</p> <p>During an observation on 03/26/2019 after 9:28 a.m., the huddle board in the kitchen was checked and the following Performance improvement projects were listed:</p> <p>1. Attendance</p> | A 283 | | | |

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| A 283 | <p>Continued From page 71</p> <p>2. Tray delivery 3. Tray accuracy 4. Starting food waste. Helping save the hospital money ...</p> <p>There was no mention of kitchen sanitation on the board.</p> <p>Dietary operation manager #133, Dietitian #119, and Dietary Director #16 reported these were the 4 PI's they were currently working on. They had been working on them for about 2 months now. The staff stated that Sodexo (dietary contracted service provider) kept their own PI's and would provide a list.</p> <p>Review of Quality minutes relating to dietary from January 2018 - February 2019 made no mention of kitchen sanitation issues, condensation issues with liquid dripping from the ceiling, or problems with sewage back up that was found in the kitchen during the survey. No list was provided during the survey to indicate PI's that Sodexo was currently working on.</p> <p>CONTRACTED SERVICES</p> <p>Review of a sample of contract evaluations on (Quest (lab), Sodexo (dietary), CAPS (pharmacy compounding service), and Steris (sterilization), and Infection Prevention and Management Associates Inc. revealed the last evaluations by the facility were dated 04/23/2018. All of the services were evaluated using the same general categories; quality, regulatory compliance, service delivery and customer service.</p> <p>During an interview on 03/26/2019 after 10:57</p> | A 283 | | | |

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| A 283 | <p>Continued From page 72</p> <p>a.m., Quality Staff #37, and #130 reported that the last time contracted services reported to quality was April 2018. A request was made to see project improvements from contracted services. Staff #130 reported that if there were any fall outs/addendums with contracted services there would be no way to see it. They were not being documented.</p> <p>SURGERY SERVICES</p> <p>Review of quality minutes revealed the following retained surgical items:</p> <p>05/2018 -lap sponge 06/14/2018- surgical towel 07/25/2018- cervical instrument 09/2018- the count sheet was revised and mandatory staff education was given.</p> <p>During an interview on 03/28/2019 after 1:35 p.m., a request was made from Quality staff #130 to see the tracking and if this was still a Performance improvement. Staff #130 stated, it was not brought forward as a PI project and there was no current tracking information on this problem.</p> <p>INFECTION CONTROL</p> <p>Review of infection control quality minutes from January 2018 - December 2018 revealed the facility was not meeting the national average when it came to some of the following infections and ways to prevent infections:</p> <p>Central line associated bloodstream infections</p> | A 283 | | | |

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| A 283 | <p>Continued From page 73</p> <p>Catheter associated urinary tract infections</p> <p>Clostridium difficile</p> <p>Methicillin-resistant Staphylococcus aureus</p> <p>Colon surgical site infections</p> <p>Hysterectomy site infections</p> <p>Isolation</p> <p>Hand hygiene</p> <p>During an interview on 03/28/2019 after 11:44 a.m., the Director of Infection control #18 confirmed the above findings.</p> <p>Infection Control Director #18 stated the following as things they identified that were not being tracked and trended:</p> <p>Chlorohexidine bathing preoperatively</p> <p>Nasal decolonization</p> <p>High level disinfecting- sterilization of equipment</p> <p>Ultrasound transducers</p> <p>Transportation of equipment</p> <p>Equipment cleaning and competencies</p> <p>Durable medical equipment</p> <p>Infection control Director #18 stated, the reason</p> | A 283 | | | |

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| A 283 | <p>Continued From page 74</p> <p>for not tracking and trending the information was because of lack of resources. Infection control Director #18 stated there was 6 Infection Preventionist to an average hospital patient census of 540.</p> <p>PHARMACY</p> <p>During the survey from 03/25-27/2019, nursing staff revealed they were discarding narcotics in biohazard boxes which were not secure. Nursing staff were observed using paper narcotic inventory sheets also which were not being completed.</p> <p>During an interview on 03/26/2019 after 9:41 a.m., Pharmacy Director#9 revealed that there was a problem with documentation of narcotic waste. The paper narcotic shift count reports were started in November 2018 as an intervention.</p> <p>Pharmacy Director #9 stated the information had not been taken to quality.</p> <p>During an interview on 03/27/2019 after 1:48 p.m., Safety Officer #154 and Pharmacy Director #9 reported the following:</p> <p>They identified they had a problem with narcotic disposal in 2016.</p> <p>CSRX narcotic disposal system was what they had decided to use. The company who they had been contracted would be out next Thursday to install the new systems.</p> | A 283 | | | |

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| A 283 | <p>Continued From page 75</p> <p>The facility's policy had been changed on yesterday for nursing staff to flush narcotics down the toilet.</p> <p>These policies had been implemented, but all nursing staff had not been trained nor had the information been taken to Medical executive committee or Governing body.</p> <p>Review of the facility's " Quality Manual 2019 " revealed the following:</p> <p>"The QMS program include, but it not limited to the following:</p> <p>A focus on indicators related to improved health outcomes and reduction of adverse events.</p> <p>An outgoing process to demonstrate measurable improvement in indicators for which there is evidence of improved health outcomes and reductions in adverse events;</p> <p>Measurement, monitoring, and analysis of quality and patient safety indicators, including adverse events, and other aspects of performance to assess processes of care, treatment, services, and operations provided; and</p> <p>Continual improvement of health outcomes and reducing risk for patients."</p> <p>Record review of the document titled, Life Safety Management Plan, effective date January 2019 showed:</p> <p>" ... 7.00 - Measuring and Improving Activities.</p> | A 283 | | | |

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| A 283 | <p>Continued From page 76</p> <p>Conditions in the environment are monitored to identify discrepancies and improve the safety and reliability of systems and processes ...</p> <p>7.03 - The Hospital Safety Officer, the Environment of Care Committee (EOCC), and the EOCC Sub-committees have established and implemented a process for ongoing monitoring of actual or potential risks in each of the management plans. To accomplish this task, data is collected and tracked and trended to see if any preventive or corrective actions need to be taken.</p> <p>Areas identified from each data is collected include, but are not limited to:</p> <ol style="list-style-type: none"> 1) Periodic Surveillance Rounds 2) Emergency and incident reporting 3) Inspection, preventive maintenance and testing of applicable equipment. <p>The EOC management plans are reviewed annually and adjusted based on changes in the environment of care, incorporating code/standards revisions and the tracked and trended indicator data. External benchmarking data will be used to further evaluate the effectiveness of the EOC system. Quality Management Oversight is given an annual report of management plan effectiveness.</p> <p>7.04 - Environment safety monitoring and response actives, as necessary, are reported to the appropriate EOC and Patient Care Committees and integrated into the overall program to improve the safety of Baylor St.</p> | A 283 | | | |

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| A 283 | <p>Continued From page 77</p> <p>Luke's Medical Center facilities for patients and all other occupants, and to enhance the healing environment."</p> <p>Record review of the document titled, 2018 Environment of Care Rounds Update, dated 08/14/2018, showed data for 2018. This report documented:</p> <p>" ...[the percent of] Compliance [for the following items]:</p> <p>37% - facility structure in safe and good condition ...</p> <p>46% - Sharps are secured - predominately 'IV Start Kits' and unlocked BMW (Biomedical Waste)</p> <p>55% - Medications are secured - predominately saline flushes</p> <p>64% - Furniture in safe and good condition ... "</p> <p>In an interview with Staff #154 on 03/29/2019 at 9:30 AM, he stated, the data collected on the quality indicators during the Environment of Care Rounds Update, dated 08/14/2018:</p> <p>1) Was presented in the Workplace Safety Committee meeting;</p> <p>2) Had not been tracked or trended; and</p> <p>3) Should have been tracked and trended to identify opportunities for improvement.</p> <p>Staff #154 also stated, there had been no tracking or trending of the quality indicators since</p> | A 283 | | | |

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| A 283 | Continued From page 78 August 2018 because environmental rounds had not been conducted. | A 283 | | | |
| A 386 | ORGANIZATION OF NURSING SERVICES CFR(s): 482.23(a) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility's nursing staff failed to: 1.) Implement physician's orders to collect stools for occult blood and application of intermittent pneumatic compression device for 1 (Patient #153) of 10 sampled patients. 2.) Ensure 5 (#23, #24, #21, #2, #18) of 10 patients were assessed for pain on admission, throughout stay, and at discharge. Findings On 04/03/2019 at 9:20 a.m., Patient #153 was observed in his room with 4 side rails up. The Patient was alert and oriented to person, place, time, and situation but contracted in his upper extremities. He had a Prevalon heel protector in place to both feet. | A 386 | | | |

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| A 386 | <p>Continued From page 79</p> <p>Review on 04/03/2019 of the Patient's clinical record, revealed a physician's order dated 03/29/2019 for stool for occult blood.</p> <p>Review of the Patient's clinical record revealed documentation which indicated, the Patient had bowel movements on 03/30/2019 at 1959 and 03/31/2019 at 2200.</p> <p>Review of the Patient's clinical record revealed no indication that the stool specimen was collected and sent to the laboratory for occult blood test.</p> <p>The Patient's clinical record was reviewed in the presence of the Unit's Nurse Manager and Registered Nurse #101 who confirmed that there was no result on the Patient's clinical record for stool for occult blood.</p> <p>Review of the Patient's clinical record, revealed a physician's order dated 03/27/2019 to "Place intermittent pneumatic compression device."</p> <p>Observation of the patient on 04/03/2019 at 9:20 a.m. revealed no evidence of an intermittent pneumatic compression device in place to the patient's legs.</p> <p>Interview on 04/03/2019 at 12.11 p.m. with Registered Nurse #182, she stated that the Patient was transferred to the unit the previous day, from the Intensive Care Unit without the intermittent pneumatic compression device and there was none available in the Patient's room. She stated " I missed the order."</p> <p>Record review of the current facility policy "Pain</p> | A 386 | | | |

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| A 386 | <p>Continued From page 80 and Opioid Management", dated 12/2018 stated:</p> <p>All patients will be reassessed for pain and adverse effects of treatment within one hours after every intervention and outcome documented. Outpatients are assessed for pain: Initial assessment is completed on arrival if indicated based on reason for visit and reassessed on an on-going basis as indicated and at discharge.</p> <p>Record review of current facility "Discharge of Patients from Emergency Services-Emergency Department (ED)" dated 01/2019, stated: If patient given initial IM/IV (intramuscular/intravenous) medication prior to discharge the patient must be observed for a minimum of thirty minutes before being discharged to assess for any adverse medication reaction. If patient has received a chemically sedating medication or anesthesia, they must have transportation through a designated driver.</p> <p>Record review on 03/25/2018 at 1135, revealed the following:</p> <p>Patient #23, 66-year-old female, was triaged on 03/24/2019 at 11:20 a.m. and medically screened at 1140 for nausea and vomiting in the emergency department (ED). Morphine 4 milligram (mg) was administered for a pain level of 7 at 4:04 p.m. Patient #23 was discharged home 4:12 p.m. from the emergency department, with her daughter.</p> <p>Patient #24, 26-year-old male, was triaged at 5:48 p.m. and medically screened at 6:57 p.m. on 03/24/2019 for abdomen pain. Patient #24</p> | A 386 | | | |

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| A 386 | <p>Continued From page 81</p> <p>received Benadryl 25 mg/IV at 9:22 p.m. and was discharged at 9:50 p.m. The documentation notes that Patient #24 was discharged by himself.</p> <p>Patient #21, 41-year-old female, was triaged on 11/28/2019 at 11:44 p.m. and medically screened 2:50 a.m. on 11/29/2018, in the emergency department for abdominal pain. On 11/29/19 at 11:42 p.m., the pain level was assessed at 10 and Patient #21 received Toradol 30 mg /IV at 03:20 a.m. on 11/30/2018 and was not reassessed until 05:24 a.m. Patient #21 was transferred to observation on 05:41.</p> <p>Patient #2, 31-year-old female, was triaged for abdominal pain on 11/29/18 arrived at 19:50 p.m., triaged 19:59 p.m., medically screened at 11:40 p.m., the pain level was not assessed until 02:18 a.m. with a level of eight (8). Morphine 2 mg, IV was ordered at 02:39 a.m. and administered at 04:41 a.m. for a pain level of nine (9). Upon reassessment the pain level was 4 at 04:58 a.m. Discharged home on 11/30/2018 at 05:28 p.m.</p> <p>Patient #18, 81-year-old male, was triaged at 11/29/2018 at 11:06 a.m. and medically screened at 10:00 a.m. for leg and right foot pain. The pain level was assessed 11:08 a.m. of 5, Tylenol #3, one (1) tablet was given at 18:44 p.m. and reassessed at 18:49 p.m. with a level of 5. Patient #18 was discharged 18:51 p.m. with spouse.</p> <p>Interview at 03/24/2019 at 1140 with RN #52, he stated, "we are supposed to reassess within the hour after giving narcotics. I would personally reassess within 15 minutes for patients with pain to ensure they have not had a reaction. We have to confirm these things before they are sent</p> | A 386 | | | |

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| A 386 | Continued From page 82 home". | A 386 | | | |
| A 392 | STAFFING AND DELIVERY OF CARE CFR(s): 482.23(b) The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure adequate numbers of Registered Nurses for supervision of patients at the Kirby Glen Center during 03/11-04/01/2019. The facility failed to provide enough staff to supervise a patient who was receiving a blood transfusion (Patient #92). The facility failed to provide enough staff to supervise patients who were receiving chemotherapy and blood transfusions. The facility failed to have an accurate staffing plan for staff to follow. This deficient practice had the likelihood to cause harm to all patients receiving treatments at the Kirby Glen Center. Findings: | A 392 | | | |

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| A 392 | <p>Continued From page 83</p> <p>During an observation on 03/27/2019 after 10:31 a.m., Patient #92 was observed to have a blood transfusion started by RN #127. Patient #92 informed RN #127 it was his first time receiving blood.</p> <p>RN #127 primed the intravenous tubing with normal saline and then started the blood transfusion. RN #127 explained the symptoms of a blood transfusion reaction to Patient #92 and stated she was starting a timer. RN#127 told Patient #92 she would be back. RN #127 started the blood transfusion and left the room. RN #127 went to another patient's bay and closed the privacy curtain and took care of that patient. RN #113 and #115 were working on the unit. RN #113 was administering chemotherapy to a patient and the privacy curtain was pulled. RN #115 was in the phlebotomy room with the door closed.</p> <p>At 10:48 a.m. (17 minutes later), RN #127 checked on Patient #92 and immediately left the room to go and help with the consent process on another patient.</p> <p>At 11:00 a.m. (29 minutes later), RN#127 returned to Patient #92's room to take vital signs.</p> <p>During interviews on 03/27/2019 after 11:00 a.m., the following was stated about staffing:</p> <p>"We need help of at least 2 more nurses. If wound care is open the nurse's aide goes to help them. The average daily census is from 15-20 patients. A nurse could have up to 4 patients who are receiving blood, chemotherapy, or injections."</p> <p>"We have 2 nurses, but that's not enough. It</p> | A 392 | | | |

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| A 392 | <p>Continued From page 84</p> <p>always takes 2 nurses just to check off on blood and chemotherapy along with other duties."</p> <p>Review of time sheets from 03/11-04/01/2019 revealed the following:</p> <p>On 03/18/2019, there were 2 nurses scheduled. One nurse had a patient scheduled at 10:00 a.m. to receive chemotherapy and another patient scheduled later at 10:30 a.m. to receive 2 units of blood. This did not include the other scheduled procedures.</p> <p>On 03/19/2019, there were 2 nurses scheduled. One nurse had a patient scheduled at 9:30 a.m. to receive 2 units of blood and another patient scheduled at 10:00 a.m. to receive 2 units of blood.</p> <p>On 03/22/2019, one nurse had a patient scheduled at 9:00 a.m. to receive 2 units of blood, and another patient scheduled at 9:30a.m. to receive chemotherapy, and another patient scheduled at 10:00 a.m. to receive 2 units of blood.</p> <p>03/26/2019, there were 2 nurses scheduled. One nurse had a patient scheduled at 9:00 a.m. to receive 2 units of blood, and another patient scheduled at 9:30a.m. to receive chemotherapy. Another nurse had a patient scheduled at 10:00 a.m. to receive 2 units of blood, and another patient scheduled at 10:30a.m. to receive chemotherapy.</p> <p>There were only two Registered nurses working 11 out of 16 days during this time frame. There</p> | A 392 | | | |

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| A 392 | Continued From page 85 was a nurse's aide added 6 out of 16 days. Review of an undated "Staffing Plan for Kirby Glen" revealed there should be a "minimal level of 2 RN's at all times In general, at about 18-20 patients, a third RN is added." Review of a facility's "Scope of Service" dated 02/13/2019 revealed the core staffing was to be a registered nurse and the patient ratio would be 1:4. The staffing plans made no mention of using nurses' aides. There were discrepancies between the two staffing plans. | A 392 | | | |
| A 395 | RN SUPERVISION OF NURSING CARE CFR(s): 482.23(b)(3) A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, nursing staff failed to: A.) Supervise and evaluate care on 1 (Patient #92) of 2 patients observed for transfusion services at the Kirby Glen Center. Patient #92 did not receive supervision immediately after the initiation of a blood transfusion for possible transfusion reactions. The facility failed to ensure timely vital signs after the initiation of the blood transfusion. B.) Supervise and evaluate the nursing care for | A 395 | | | |

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| A 395 | <p>Continued From page 86</p> <p>each patient, as Emergency department (Main ED) patients were not seen in order of acuity, physician's orders were not carried out in a timely manner, and assessments/reassessments of patients were not performed according to facility policy on Patient #17, #160, and #162.</p> <p>C.) supervise and evaluate care for 1 (Patient #52) of 10 patients records reviewed that reflected pain medication orders that did not contain physician directive for use and the nurse did not clarify the order prior to giving the medication for pain.</p> <p>This deficient practice had the likelihood to cause harm to all patients.</p> <p>Findings:</p> <p>During an observation on 03/27/2019 after 10:31 a.m., Patient #92 was observed to have a blood transfusion started by RN #127. Patient #92 informed RN #127 it was his first time receiving blood.</p> <p>RN #127 primed the intravenous tubing with normal saline and then started the blood transfusion. RN #127 explained the symptoms of a blood transfusion reaction to Patient #92 and stated she was starting a timer. RN#127 told Patient #92 she would be back. RN #127 started the blood transfusion and left the room. The blood transfusion reaction form was placed underneath the mobile computer.</p> <p>RN #127 went to another patient's bay and closed the privacy curtain and took care of that patient. RN #113 and #115 were working on the unit. RN #113 was administering chemotherapy to a</p> | A 395 | | | |

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| A 395 | <p>Continued From page 87</p> <p>patient and the privacy curtain was pulled. RN #115 was in the phlebotomy room with the door closed.</p> <p>At 10:48 a.m. (17 minutes later), RN #127 checked on Patient #92 and immediately left the room to go and help with the consent process on another patient.</p> <p>At 11:00 a.m. (29 minutes later), RN#127 returned to Patient #92's room to take vital signs.</p> <p>During an interview after 11:00 a.m., Staff #127 confirmed, she was supposed to stay with the patient for the first 15 minutes or have someone supervise the patient. Staff #127 stated, she was supposed to be completing the form during the transfusion. Staff #127 was shown the instructions on the pink sheet (Blood Transfusion Real-Time Checklist/Audit Tool).</p> <p>Review of checklist revealed a category for pre-transfusion documentation, dual nurse verification, intra- infusion documentation, reaction documentation, symptoms of a possible transfusion reaction, and completion documentation.</p> <p>There was documentation on the checklist that staff were to sign the sheet indicating it was used during the transfusion. There was documentation on the checklist that vital signs were to be taken 15 minutes after initiation of the blood transfusion.</p> <p>B. The clinical records for 10 emergency department patients were reviewed (patients #17 - #23, patient #160, and patient #162).</p> <p>Patient #17 presented to the facility ED (Main ED)</p> | A 395 | | | |

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| A 395 | <p>Continued From page 88</p> <p>on 1-15-19 at 1:50 pm, by private vehicle with a chief complaint of lung problems and shortness of breath. He was assigned an emergency severity index of II. Online reference https://www.esitriage.com/esi-algorithm states, "The Emergency Severity Index (ESI) is a five-level emergency department (ED) triage algorithm that provides clinically relevant stratification of patients into five groups from 1 (most urgent) to 5 (least urgent) on the basis of acuity and resource needs."</p> <p>Patient #17 saw the physician at 1:59 pm. The physician ordered lab work, a chest x-ray, an EKG [electrocardiogram], a Proventil nebulizer treatment, a Duo-Neb nebulizer treatment, and Solu-Medrol 125 mg intravenously. Although intravenous access was established within minutes of the order, the ordered medications were not administered until 5:18 pm. No documentation was provided to explain the 3 hour, 19 minute delay in carrying out the physician's orders.</p> <p>The patient's vital signs were assessed at the following times: * 1:53 pm * 3:40 pm</p> <p>No other documentation of vital sign assessment was found.</p> <p>After waiting in the waiting room for 6 hours and 31 minutes, patient #17 was placed in ER room #A-06 at 8:30 pm. Additional medication was ordered at 8:56 pm and given at 9:06 pm.</p> <p>Patient #17 was discharged from the emergency department at 9:49 pm. He was given</p> | A 395 | | | |

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| A 395 | <p>Continued From page 89</p> <p>prescriptions along with his discharge instructions.</p> <p>A review of 2 additional clinical records revealed the following:</p> <p>* Patient #160 arrived at the ED on 1-15-19 at 3:14 pm. The patient was assigned an emergency severity index of 5. The patient was placed in an ED room at 3:54 pm, seen by the physician at 4:38 pm and discharged at 5:20 pm.</p> <p>* Patient #162 arrived at the ED on 1-15-19 at 4:28 pm. The patient was assigned an emergency severity index of 2. The patient was placed in an ED room at 4:35 pm, seen by the physician at 4:49 pm and discharged at 8:56 pm.</p> <p>Facility policy titled "Discharge of Patient from Emergency Services - Emergency Department" states, in part:</p> <p>"Policy</p> <p>...</p> <p>B. Vital signs including pain level will be assessed within one hour prior to discharge and any significant changes reported to provider."</p> <p>Facility policy titled "Treatment Area Reassessment Guidelines - Emergency Department" states, in part:</p> <p>"Procedures</p> <p>...</p> <p>2. Reassessments:</p> <p>i. The frequency of reassessment is initially based on the patient's acuity and adjusted as the</p> | A 395 | | | |

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| A 395 | <p>Continued From page 90</p> <p>patient's condition improves or worsens.</p> <p>ii. Reassessment parameters are based on the patient's presenting condition, and typically include but are not limited to pulse, respiratory rate, blood pressure, pulse oximetry and pain assessment minimally every four (4) hours."</p> <p>Facility policy titled "Triage - Emergency Department" states, in part:</p> <p>"Procedures</p> <p>A. All patients arriving in Baylor St. Luke's Medical Center (BSLMC) Emergency Department (ED) or Community Emergency Centers (CECs) will be seen and evaluated by an RN for purposes of prioritizing patient care. The RN will assign the patient an appropriate triage acuity level based on the Emergency Severity Index (ESI)."</p> <p>Patient #52's record reflected: "3/26/19...9:45 AM Pain Score: 10...9:46 AM Methadone 10 mg (given/milligrams)...Order: Methadone 10 Mg every 6 hours, PRN (as needed) for severe pain."</p> <p>There was no pain scale associated to the Methadone order to discern when the medication was supposed to be used.</p> <p>During record review and interview on 3/26/19 ending at 10:30 AM, the navigator, RN #97 confirmed the above finding and stated, "we are supposed to call the doctor for clarification, if an order doesn't include the pain scale."</p> <p>The facility's 2 page, undated, laminated</p> | A 395 | | | |

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| A 395 | Continued From page 91 "Education" required, "Pain Assessment...Make sure the pain scale correlates with the type of pain medication the MD (doctor) ordered...if your patient has a pain scale of 7 you must get an order to correlate with that pain score..." The facility's February 2019 "Medication Administration" policy required, "The RN is responsible for reviewing and performing any clarification of medication orders...once reviewed, the RN will acknowledge and release orders in the electronic health record..." | A 395 | | | |
| A 396 | NURSING CARE PLAN CFR(s): 482.23(b)(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure a current and up-to-date nursing care plan for each patient, in that, 2 (Pt #52, and #54) of 10 patients' records did not document a current and up-to-date nursing care plan. Findings: ~ Patient #52's record reflected: "ED (Emergency Center) Provider Notes: 3/25/19...Chief Compliant...Urinary Retention over 2 weeks. Pt with lower abdomen pain...also concerned about blood pressure...71 year-old...Past Medical History...Hypertension...Physical Exam: (Blood Pressure) B/P 130/91...Pulse | A 396 | | | |

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| A 396 | Continued From page 92 107...Cardiovascular...Tachycardia...8:45 PM (Physician Name) accepts admit..." Further review of the patient's inpatient record revealed there was no nursing care plan for urinary retention or cardiac issues. During record review and interview on 3/26/19 ending at 10:30 AM, the navigator, RN #97 confirmed the above findings. ~ Patient #54's record reflected: "3/23/19 History and Physical...69 year-old...cirrhosis...ascites...getting paracentesis...dehydration...complaining of nausea and vomiting and inability to tolerate oral intake..." During record review and interview on 3/26/19 ending at 3:20 PM, the navigator, RN #101 was asked if the patient had a wound. RN #101 confirmed a Stage II, Coccyx with foam dressing applied. RN #101 was asked for the nursing care plan for the wound. RN #101 stated, "I don't find one for the wound, no skin integrity started." | A 396 | | | |
| A 405 | ADMINISTRATION OF DRUGS CFR(s): 482.23(c)(1), (c)(1)(i) & (c)(2) (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice. (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such | A 405 | | | |

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| A 405 | <p>Continued From page 93</p> <p>practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</p> <p>(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure drugs were administered in accordance with hospital policies about pain management and follow-up, in that,</p> <p>A) 2 (Patient #51 and #55) of 10 patients' medical record did not reflect pain medication given for a pain response when medication was ordered.</p> <p>B) 1 (Patient #52) of 10 patient's medical records did not reflect pain management follow-up after pain medication administration.</p> <p>Findings:</p> <p>A) Patient #51's record reflected, "Pain Score: 5 (Five/score given by patient)...3/26/19...10:37 AM...Orders: Norco 325 mg for pain of 4-6..."</p> <p>There was no pain medication given for their pain.</p> <p>During record review and interview on 3/26/19 ending at 10:30 AM, the navigator, RN #97</p> | A 405 | | | |

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| A 405 | <p>Continued From page 94 confirmed the above finding.</p> <p>Patient #55's record reflected: "3/26/19...7:05 AM Pain Score: 9...Orders: Morphine 30 mg PO q 6 hours for scale 7-10/severe pain."</p> <p>There was no pain medication given for their pain.</p> <p>During a record review and interview on 3/26/19 ending at 3:20 PM, the navigator, RN #101 confirmed the findings.</p> <p>The facility's December 2018 "Pain and Opioid Management" policy required, "Right to effective pain management and will be assessed for the presence of pain on admission, regularly throughout their stay, and on discharge...be reassessed for pain and adverse effects of treatment within one hours after every intervention and outcome documented."</p> <p>B) Patient #52's record reflected: "3/26/19...</p> <p>2:37 AM Pain Score: 10...2:37 AM Tramadol 50 Mg (milligrams/given)...</p> <p>9:45 AM Pain Score: 10...9:46 AM Methadone 10 mg (given)..."</p> <p>There was no reassessment for pain/adverse outcome/effects of treatment documented after either of these administrations.</p> <p>During record review and interview on 3/26/19 ending at 10:30 AM, the navigator, RN #97 confirmed the above finding and stated, "we are</p> | A 405 | | | |

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| A 405 | Continued From page 95 supposed to reassess within 60 minutes." | A 405 | | | |
| A 438 | <p>FORM AND RETENTION OF RECORDS CFR(s): 482.24(b)</p> <p>The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.</p> <p>This STANDARD is not met as evidenced by: Based on review of medical records of patients that died in the hospital, the medical records of 4 (Pt. #172, 179, 174, and 175) out of 10 (Pts #170, 171, 172, 179, 173, 174, 175, 176, 177, and 178) deceased patients failed to contain accurate information regarding the patients.</p> <p>Findings:</p> <p>Patient #179. The patient was admitted to the hospital on 12/11/2018 and died on 1/23/2019. The surgical history section of the History & Physical completed by the physician failed to include the lung transplant the patient had. Further review of the medical record showed that the patient had bilateral lung transplant on 11/28/2013 and 6/25/2017. The Discharge Summary was completed by a Physician's Assistant on 1/23/2019 and countersigned by a physician on 01/24/2019. The Discharge Summary showed the "Disposition" as "Home or Self Care."</p> <p>Patient #174. The patient was admitted to the</p> | A 438 | | | |

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| A 438 | Continued From page 96 hospital on 11/13/2018 and died on 11/17/2018. The History & Physical completed by a physician failed to include the chief complaint of the patient. The Discharge Summary completed by a physician failed to include the date and time. The medical record showed that the patient was eligible for tissue donation. There was no documentation what tissues were harvested or where the tissues were harvested, and who harvested the tissues. The medical record failed to show what happened to the patient as there was no indication whether the patient was transferred to the morgue or to a funeral home. After the hospital staff did some investigation, it was discovered that the patient was sent to the morgue, and a tissue bank picked it up and took it to their facility where skin grafts, cornea, and whole eye were harvested. There was no consent from the family for the release of the body to the tissue bank. The tissue bank released the body to a funeral home. Patient #178. The patient was admitted to the hospital on 9/2/2018 and died on 9/11/2018. The Discharge Summary showed the examination as: Eyes - PERRL, Respiratory - Intubated, Cardiovascular - Peripheral pulses intact. The Dispositon was Deceased. Patient #175. The patient was admitted on 10/21/2018 and died on 10/22/18. The patient had an autopsy but the medical record failed to include the Autopsy report. | A 438 | | | |
| A 491 | PHARMACY ADMINISTRATION CFR(s): 482.25(a) [§482.25 Condition of Participation: Pharmaceutical Services | A 491 | | | |

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| A 491 | <p>Continued From page 97</p> <p>.....The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.]</p> <p>§482.25(a) Standard: Pharmacy Management and Administration</p> <p>The pharmacy or drug storage area must be administered in accordance with accepted professional principles.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Based on observation, review of records, and interview, the facility failed to ensure:</p> <p>A. Processes for transportation of chemotherapy medications between the main pharmacy and the outpatient infusion center (Kirby Glen) that included steps to minimize potential contamination of non-chemotherapy drugs and potential employee exposure to chemotherapy drugs.</p> <p>B. Drug storage areas and medications with the potential for drug diversion were monitored and/or disposed of effectively to prevent the likelihood for medication errors and drug diversion in 5 of 5 Intensive Care Units (ICU) (Medical ICU 7S1, Medical ICU 7S2, Neuro ICU 7S4, Neuro ICU 7S5, and Cardiovascular Critical Care) observed; and unauthorized access by persons not authorized to administer medications in two (2) of three (3) emergency centers.</p> <p>Findings:</p> <p>A. On the morning of 3-27-2019, a tour of Kirby</p> | A 491 | | | |

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| A 491 | <p>Continued From page 98</p> <p>Glen outpatient pharmacy area was made with Staff #100. Staff #100 was asked how chemotherapy drugs were transported and received to the outpatient pharmacy. Plastic transportation bins were observed to be by the door of the pharmacy. Staff #100 stated, these were the bins that medications were transported in. None of the bins had markings that would indicate the bins were solely dedicated to chemotherapy medications. The inside of the top bin was visibly soiled and had liquid in the bottom of it. Staff #100 was asked if the liquid contained chemotherapy medications. Staff #100 stated, the liquid was condensation from the ice pack that had been used in the transportation of chemotherapy medications from the main pharmacy to the Kirby Glen outpatient pharmacy earlier that morning. Staff #100 showed the ice pack was being stored in a refrigerated cabinet dedicated for storage of chemotherapy medications. When asked how he could be certain that exterior of the ice pack had not been contaminated with chemotherapy medication, thereby contaminating the container during the condensation process, Staff #100 confirmed that he couldn't.</p> <p>On the morning of 3-28-2019, the Kirby Glen outpatient pharmacy was toured again with Staff #129. Staff #129 had just sealed a medication transportation container for transport to the main pharmacy. Staff #129 was asked to open the container. The container contained an ice pack at the bottom, a plastic divider sitting on the top of the ice pack, the chemotherapy medication, Doxorubicin, in one compartment of the divider, and on the other compartment were blood plasma product and Intravenous Immune Globulin. This method of transportation allowed</p> | A 491 | | | |

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| A 491 | <p>Continued From page 99</p> <p>for the potential of transfer from chemotherapy medication contamination on the outside of the icepack or the Doxorubicin package to the IVIG package via condensation. Any staff member handling the IVIG after transport could potentially become unknowingly exposed to chemotherapy agents.</p> <p>On the morning of 3-29-2019, an interview was conducted with Staff #9. Staff #9 confirmed that the pharmacy followed a variety of standards and guidelines to include the United States Pharmacopeia (USP), American Society of Health-System Pharmacists (ASHP), best practices, state board requirements and other government standards and guidelines when developing policies and practices. During interview with Staff #9 on the morning of 4-1-2019, Staff #9 stated that the pharmacy had not fully looked at the transportation of hazardous drugs, as the requirements for USP 800 (Hazardous Drugs - Handling in Healthcare Settings) did not become enforceable until December 2019. Staff #9 confirmed that the safe handling of hazardous drugs was not a new requirement and other standards and guidelines existed.</p> <p>Review of the 2004 Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) document titled, NIOSH ALERT Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was as follows:</p> <p>"Foreword</p> <p>The purpose of this Alert is to increase</p> | A 491 | | | |

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| A 491 | <p>Continued From page 100</p> <p>awareness among health care workers and their employers about the health risks posed by working with hazardous drugs and to provide them with measures for protecting their health. Health care workers who prepare or administer hazardous drugs or who work in areas where these drugs are used may be exposed to these agents in the air or on work surfaces, contaminated clothing, medical equipment, patient excreta, and other surfaces. Studies have associated workplace exposures to hazardous drugs with health effects such as skin rashes and adverse reproductive outcomes (including infertility, spontaneous abortions, and congenital malformations) and possible leukemia and other cancers. The health risk is influenced by the extent of the exposure and the potency and toxicity of the hazardous drug."</p> <p>Page 12 under Detailed Recommendations section:</p> <p>"Store hazardous drugs separately from other drugs, as recommended by ASHP (1990) and other chemical safety standards.</p> <p>Store and transport hazardous drugs in closed containers that minimize the risk of breakage.</p> <p>...</p> <p>Drug Preparation and Administration</p> <p>Initial Step</p> <p>As part of the hazard assessment described earlier, evaluate and review the entire drug preparation and administration process to identify points at which drugs might be released into the work environment. Always consider the possibility of contamination of the outside containers."</p> | A 491 | | | |

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| A 491 | <p>Continued From page 101</p> <p>B.) On 3-25-2019 at approximately 10:30 AM, a tour of 7S2, 7S4, and 7S5 ICUs was made. During the tour of the drug storage areas on 7S2, locked cabinets were observed for the storage of 1000 milliliter bags of dialysis fluids. One cabinet was labeled for dialysis fluid with a 2 milliequivalent (a unit of measure to indicate the concentration) of potassium and the other was labeled for dialysis fluid with a 4 milliequivalent (mEq) of potassium. When opened, both cabinets were filled with the 4 mEq concentration. The cabinet was locked with a punch-button key pad, allowing a staff member with the combination to remove the fluid without having to scan the bags of fluid or record the removal in the Automated Dispensing Machine (ADM) computer system.</p> <p>An interview was conducted with RN #11 at the time of the tour. RN #11 stated, he was not aware that the dialysis fluids were being stored in the wrong cabinet. RN #11 stated that patients were not at risk of receiving the 4 mEq concentration instead of the 2 mEq concentration because there was a "hard stop" in place. RN #11 stated that nursing staff had to scan medication prior to administration. The process RN #11 described was not a hard-stop. There was a likelihood for nursing staff to remove the incorrect concentration of fluid from the cabinet without scanning the bag to check against the patient orders in the ADM. It was possible for nursing staff to connect the bag of incorrect concentration to a dialysis machine without scanning the bag in the ADM against the patient orders.</p> <p>An interview was conducted with Staff #22 on the afternoon of 3-28-2019. Staff #22 confirmed that</p> | A 491 | | | |

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| A 491 | <p>Continued From page 102</p> <p>pharmacy staff were required to look at medication storage areas daily and when doing "everyday rounds". Staff #22 stated that pharmacy staff looked at the ADMs but must have missed the storage areas for the dialysis fluids.</p> <p>Review of Policy and Procedure Title: Drug Storage Requirements, Monitoring, and Inspection - Pharmacy; Effective: February 2019; was as follows:</p> <p>"POLICY</p> <p>The Pharmacy shall be responsible for the safe and proper storage and preparation of pharmaceutical agents in the hospital. Monitoring and recording of temperatures shall be performed continuously in all pharmacy drug storage areas, to include refrigerators and freezers. Refrigerators and freezers in patient care areas, procedural areas and clinics that may store vaccines are also monitored continuously; other areas are monitored daily. All pharmacy and institutional drug storage locations shall be inspected by pharmacy personnel routinely, with documented results provided to the appropriate area manager. "</p> <p>During the same tour, the Narcotic Count sheets were observed on units 7S1, 7S2, 7S4, and 7S5 to have numerous missing documentations of narcotic counts without explanation on the form. The instructions on the Narcotic Count Sheet showed that each shift at shift change, an RN from the night shift, and RN from the Day shift were required to count the remaining narcotics in all of the drawer that had been accessed during</p> | A 491 | | | |

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| A 491 | <p>Continued From page 103</p> <p>the off-going shift. Once a week on Tuesdays, a full count of all narcotics in the ADM were required to be counted by two (2) RNs. Weekly inventory counts should have been done on 3-5-2019, 3-12-2019, and 3-19-2019. Review of the form was as follows:</p> <p>7S1 12 out of 50 shift checks had not been documented. The 3-12-2019 weekly count was not completed until 3-13-2019.</p> <p>7S2 5 out of 50 shift checks had not been documented. The 3-12-2018 weekly count was not completed until 3-16-2019.</p> <p>7S4 18 out of 50 shift checks had not been documented. The weekly count had not been documented since 3-5-2019.</p> <p>7S5 19 out of 50 shift checks had not been documented. No weekly counts were documented.</p> <p>RN #25 was interviewed during the tour about the purpose of the narcotic counts and the missing narcotic checks on unit 7S1. RN #25 stated, the narcotic counts were required to immediately identify any discrepancies with missing narcotics. RN #25 stated that this was probably due to no narcotic drawers being opened during the shift or that the count was done and nursing staff had forgotten to document the form. RN #25 was asked how she would know. RN #25 confirmed that she was aware that some of the counts were missed and stated that this was discussed at</p> | A 491 | | | |

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| A 491 | <p>Continued From page 104</p> <p>huddle. When asked if this problem was going through the quality/process improvement process, RN #25 stated that she knew it was an opportunity for improvement, but could not provide documentation of how the problem was being tracked, data was being aggregated and analyzed, or how the resolutions attempted were being monitored for effectiveness.</p> <p>A request was made for Pharmacy to run a report showing the narcotic access and counts to be compared to the counts documented on the Narcotic Count sheets.</p> <p>Staff #22 was interviewed on the afternoon of 3-27-2019 during a meeting about potential drug diversion. Staff #22 confirmed that the requested report had been run and that counts had been missed. Staff #22 stated that Staff #68 reviewed narcotic count discrepancies daily and tracked on a weekly basis. Reports were sent weekly to leadership. Staff #22 confirmed that once the reports were sent to leadership, there was no required response back to Pharmacy concerning the resolution, therefore, Pharmacy was not aware of how the problems with narcotic counts were being managed on the units.</p> <p>Gaps in security controls of narcotics provide opportunities for a staff member to exploit the controls to divert drugs and go unidentified in the event of an incorrect narcotic count.</p> <p>The policy that outlined the process and time-frames for narcotic counts was requested. The Policy and Procedure Title: Controlled Drug Systems and Accountability - Pharmacy, Effective: February 2019, was provided with a note that indicated narcotic counts were</p> | A 491 | | | |

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| A 491 | <p>Continued From page 105 addressed in section 1.e and 4.b. Review of those sections was as follows:</p> <p>"PROCEDURES</p> <p>1. Ordering and Receiving Controlled Drugs ... e. All controlled drugs will be entered into the secured narcotic tracking and storage system records and th4e inventory balance will be adjusted accordingly.</p> <p>4. Accountability of Controlled Drugs</p> <p>a. A perpetual inventory record will be maintained on all controlled drugs stored in the controlled drug vault area utilizing the secured controlled drug tracking and system.</p> <p>b. Audits of these inventories will be performed monthly to assure that physical counts match the counts in the secured narcotic tracking and storage system."</p> <p>The policy did not address the process for accounting for narcotics on the units each shift and weekly to prevent drug diversion and quickly identify potential problems with missing narcotics.</p> <p>On the afternoon of 3-29-2019, further interview was conducted with Staff #22 concerning Pharmacy efforts to prevent potential drug diversion. Staff #22 stated that she had been working with nursing to identify potential problems with the use of continuous Intravenous (IV) narcotics infusions. A tour of the Cardiovascular Critical Care unit was made. Pharmacy and nursing had identified that the drugs, Ativan and</p> | A 491 | | | |

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| A 491 | <p>Continued From page 106</p> <p>Versed, were packaged in a way that would allow staff to access the medication. Lock boxes had been ordered to prevent this potential diversion route. However, the IV administration tubing that was being used in the ICUs and Critical Care area allowed for staff to be able to access a port (opening) in the IV administration tubing (open tubing), remove medication, and replace it with a compatible solution without having to change the count of the amount of drug given. This would allow a staff member to dilute the drug; while the fluid amount given to the patient would remain the same. The same accessible open tubing was being used for the drug Diprivan. While Diprivan was not a narcotic, it had a high potential for abuse and was counted/managed as a narcotic by Pharmacy.</p> <p>Interview was conducted with Staff #22 and RN #90 during the tour and observations. Staff #33 and RN #90 both confirmed that the accessibility to divert medications using the open tubing system rather than a closed tubing system had not been considered.</p> <p>A tour was conducted of unit 7 South 1 & 2 on 3/25/19 at 10:25AM. Review of the drug storage and medication preparation area revealed there was no drug disposal system noted for wasting narcotics. RN #28 was asked by the surveyor how the nurse wasted narcotics. RN #28 reported that the liquids are wasted in the sink and signed off by two nurses. RN #28 was asked what about a tablet or a patch such as a morphine patch. RN #28 stated, "I guess you would just waste it down the sink." RN #28 was asked by the surveyor if it's a whole pill you dropped or patch how would you put that down the sink? RN #28 reported she wasn't sure and stated, "Well, I think if you</p> | A 491 | | | |

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| A 491 | <p>Continued From page 107</p> <p>dropped a pill or removed a patch you would just put it in the red box in the patient's room." RN #28 confirmed the red box was the plastic red container that hangs on the wall in the patient's room. The container is for used sharps such as needles. The containers are not locked down and had an opening for access.</p> <p>An interview was conducted with RN #29 on 3/25/19 at 10:35 AM. RN #29 was asked how a narcotic pill or patch is wasted. RN #29 stated, "I'm not sure. I have never had to waste a pill here so I guess I would call the pharmacy and ask what to do." RN #29 confirmed she would probably put a patch in the sharps container in the patient rooms.</p> <p>An interview was conducted with Staff #6 on 3/25/19 at 10:40 AM. Staff #6 stated, "This has been an issue and there has been discussions about it but I'm just reluctant to speak to it."</p> <p>An interview was conducted with RN #11 on 3/25/19 at 10:45 AM. RN #11 stated he knows where the nurses are disposing of the narcotics. RN #11 walked the surveyors in a soiled utility room and pointed to a black plastic container on the wall. The plastic containers had labels that stated, "Hazardous Compatible Pharmaceutical Waste." (This room was not secured and multiple employees had access to this room including, housekeeping, maintenance, and contracted companies.). The surveyor asked RN #11, are you sure that this is where the narcotics are discarded and does the contracted company know that narcotics are disposed of in these containers? RN #11 confirmed, "Yes." The surveyor showed RN #11 the label on the containers that stated, "No controlled</p> | A 491 | | | |

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| A 491 | <p>Continued From page 108</p> <p>substances." RN #11 stated, "Oh well maybe that's not where they are discarded."</p> <p>Staff #29 looked up the policy on the computer and showed the surveyor the policy. Policy "Medication Administration February 2019" stated,</p> <p>"i. To waste controlled substance solutions, the nurse will use a syringe to withdraw the medication from the container and measure the amount to be wasted, with a second nurse as witness to the process.</p> <p>ii. The wasted solution is discarded in the sink and rinsed away.</p> <p>c. Disposal of transdermal patches containing opiate analgesic will include folding patch and depositing the discarded patch in the sharps container. This should be done after donning gloves, and is observed by the witnessing nurse and co- signed on the appropriate record."</p> <p>An interview was conducted with RN #28 in the morning of 3/25/19. RN #28 reported when the containers are full they are to be picked up by an outside contracted company. RN #28 was asked if it was housekeeping that goes into the rooms to pick up the containers or the actual contracted company? RN #28 stated, "I'm pretty sure it's ____ (contracted company) people that go in and get them. We call down to housekeeping to let them know if one is full but they come by pretty often."</p> <p>An interview was conducted with Staff #31 in the morning of 3/28/19. Staff #31 reported that Environmental Services (EVS) occasionally receive calls that sharp containers are full and</p> | A 491 | | | |

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| A 491 | Continued From page 109 need to be picked up. EVS will contact ____ (contracted company) to pick up. The contracted company goes into the patient's rooms to pick up the containers. Staff #31 was asked if the contracted company was aware narcotics were in the sharp containers and how do they ensure the containers are protected from drug diversion? Staff #31 stated, "Oh no. They don't pick up narcotics. Narcotics are not supposed to be in the sharps containers." Staff #31 was informed of the nurse interviews and policy. Staff #31 confirmed he was not aware of this. Findings for Emergency Centers: Record review of the policy Drug Storage Requirements, Monitoring and Inspection-Pharmacy, dated February 2019. "Access to the designated medication storage is limited to personnel who are authorized to handle medications." Observation of the Holcombe Emergency Center on 03/27/2019 and the Pearland Emergency Center on 03/29/2019 revealed the designated medication storage area housed the copy machine, the Pyxis, patient nutrition, oxygen and other supplies. Interview on 03/27/2019 at 11:00 a.m. with interim Nursing Emergency Director (Staff #116) for the Emergency Center, the Director confirmed that front desk personnel as well as the medical technicians had access to the area. | A 491 | | | |
| A 618 | FOOD AND DIETETIC SERVICES CFR(s): 482.28 The hospital must have organized dietary | A 618 | | | |

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| A 618 | <p>Continued From page 110</p> <p>services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.</p> <p>This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility's Dietary Services failed to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. The facility failed to:</p> <p>A.) Ensure the staff followed safe food handling policies.</p> <p>B.) Ensure that the facility's two large mechanical dish washers were repaired and the contaminated dishware were not utilized.</p> <p>C.) Ensure food was not being prepared in areas when the sewer drains were backing up or where water was draining from the ceiling.</p> <p>D.) Ensure the kitchen staff does not use equipment and dishware that had not been properly cleaned, repaired, or were in need of replacement.</p> <p>These deficient practices were determined to pose an Immediate Jeopardy and placed all patients receiving meals from the facility's kitchen</p> | A 618 | | | |

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| A 618 | Continued From page 111 at an increased risk of biological, physical and chemical cross contamination leading up to injury, nausea, vomiting, diarrhea, and the possibility of death. | A 618 | | | |
| A 619 | Refer to A0619 ORGANIZATION CFR(s): 482.28(a) Organization This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to provide Food Services in a safe and sanitary condition as evidenced by: A.) The walk-in refrigerator #68, which contained the milk products used for the patients, was not maintaining adequate temperatures, placing patients at risk of receiving spoiled dairy products. B.) The facility's two large mechanical dish washers were building up copious amounts of steam that was condensing and dripping off the dirty ceiling tiles onto the cleaned dishware, placing the patients at risk of eating off of contaminated dish wares, and water was draining from a ceiling tile in the pots and pans dish washing area. C.) The kitchen's sewage drains had been routinely backing up into the patient food production areas, placing patients at risk of consuming contaminated foods. D.) The dirty pots and pans were stored wet and available for use, molded vegetables were | A 619 | | | |

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| A 619 | <p>Continued From page 112</p> <p>available for use, and the floors and kitchen equipment were coated in dirty grease and old food particulates creating an unsanitary environment.</p> <p>These deficient practices were determined to pose Immediate Jeopardy to patient health and safety, and placed all patients at risk for the likelihood of harm, serious injury, and possible subsequent death.</p> <p>Findings:</p> <p>A.) Review of the facility Refrigerator and Freezer Monitoring policy (revision date February 2019) reflected, " ...The hospital maintains an appropriate number of refrigerator and heating devise, and ensures that food ... are stored properly and in accordance with nationally accepted guidelines (food) ...</p> <p>e. If the current minimum or maximum temperature reading of a specific refrigerator is out of range, immediate action is needed.</p> <p>i. For a food and nutrition refrigerator:</p> <ol style="list-style-type: none"> Using a calibrated thermometer properly check the temperature of the perishable food item inside the refrigerator/freezer. Immediately relocate perishable food items that are temping above 41 degrees Fahrenheit/ 0 degrees Fahrenheit (freezer) to an operative refrigerator. Decommission refrigerator/freezer and document on the corrective action "Unit out of Service" with work order number. Discard perishable food and check the box | A 619 | | | |

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| A 619 | <p>Continued From page 113 next to 'Discard Perishable Food'.</p> <p>4. Enter a Facilities Work Order and request to service the equipment for any refrigerator/freezer observed to be out of temperature range</p> <p>5. Document corrective action and notification of coordinator on temperature log.</p> <p>6. Enter an IRIS report ..."</p> <p>3. Refrigerator and freezer temperatures shall be maintained within the following ranges: ... i. Refrigerator: 36 to 46 degrees Fahrenheit"</p> <p>Review of the facility provided Food Establishment Inspection Report dated 1/14/19 reflected, "Restore walk in cooler to provide proper holding temperature 41 degrees Fahrenheit"</p> <p>An observation on the morning of 3/25/19 in the facility's Dietary Department revealed the Cooler #68 was registering a temperature of 50 degrees Fahrenheit. The surveyor removed an individual patient's milk carton from Cooler #68 and requested the staff check the temperature of the milk. The staff inserted a thermometer, the milk registered 48 degrees Fahrenheit. Further observation revealed copious amounts of ice built up on the internal evaporative cooling system.</p> <p>During an interview on the afternoon of 3/25/19, in the facility's kitchen, when asked what was wrong with Cooler #68, Staff #23 stated, " ...We added Freon to the cooler ... it's a closed system ... it shouldn't lose Freon, once it leaks you have to watch it We serviced it back in August"</p> | A 619 | | | |

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| A 619 | <p>Continued From page 114</p> <p>During an interview on the morning of 3/25/19, in the facility's kitchen, Staff #17 stated, "I put the work order in this morning ... I didn't report it, usually I will report it to the head chef"</p> <p>During an interview on the morning of 3/25/19, in the facility's kitchen, Staff #16 confirmed the milks were not moved to a working cooler, were not discarded, and had been available for use. On the morning of 3/26/19, in the facility's kitchen, Staff #16 confirmed the milks had been removed and discarded and that two (2) cases of refrigerated puddings had been left in the cooler and were still available for use.</p> <p>Review of the facility provided maintenance records reflected the following work orders:</p> <p>Refrigerator Cooler #68 work orders from 7/24/18 to 3/25/19</p> <p># 2859447 on 3/25/19 at 7:22 am," Cooler #68 (milk cooler) has flake snow built up on the evaporator."</p> <p>#2855735 on 3/22/19 at 1:37 pm, "Milk Cooler #68 Alarm ... waited for temp to drop maybe in defrost 15. Minutes didn't drop found door crack open close door." The work order was not assigned to a maintenance employee</p> <p>#2851270 on 3/19/19 at 10:11 am, "Cooler #68 (milk cooler)" Maintenance responded on 3/20/19 at 8:28 pm.</p> <p>#2842276 on 3/13/19 at 11:54 am, "Walk in Milk Cooler #68 has ice buildup on evaporator."</p> | A 619 | | | |

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| A 619 | <p>Continued From page 115</p> <p>Maintenance responded on 3/14/19 at 2:00 pm.</p> <p>#2833838 on 3/7/19 at 4:13 pm, "Cooler #68 (milk cooler) has ice on evaporator." Maintenance responded on 3/7/19 at 5:26 pm.</p> <p>Cooler #68 Work Orders from 7/24/18 to 8/14/18</p> <p>#2497496 on 8/14/18 at 10:40 am, "Coolers #68 and #83 are warm temperatures." Maintenance responded on 8/27/18 at 10:16 am.</p> <p>#2482716 on 8/2/18 at 8:54 am, "cooler #68 the milk box is not running and temp is at 50 degrees. Can someone be sent up ASAP Thanks." Maintenance responded on 8/3/18 at 1:50 pm.</p> <p>#2482694 on 8/2/19 at 8:33 am, "LARGE COOLER 68 TEMP IS 50 WE." OUR MILK FOR PATIENT SERVICES URGENT REPAIR." Maintenance responded on 8/2/18 at 7:45 pm.</p> <p>#2464829 on 7/25/18 at 5:47 pm, "Milk Cooler #68 has freezing evaporator issue." Maintenance responded on 7/25/18 at 9:08 pm.</p> <p>#2463219 on 7/24/18 at 2:14 pm, "Cooler #68 (Milk box) is frosting up on the evaporator." Maintenance responded on 7/24/18 at 5:25 pm.</p> <p>B.) An observation on the morning of 3/26/19, in the facility's dish washing room revealed two large mechanical dish washers that were moving dishes through on conveyor tracts. The two dish washers were building up copious amounts of steam that was condensing and dripping off the</p> | A 619 | | | |

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| A 619 | <p>Continued From page 116</p> <p>dirty ceiling tiles onto the cleaned dishware, pots and pans The Pots and Pans room had water leaking from a ceiling tile; mold was found on the tiles from previous leaks.</p> <p>Further observations revealed rust on the pipes and metal railings above the washers, an indication that the water had been an ongoing issue.</p> <p>During an interview on the morning of 3/26/19, in the dishroom, Staff #16 and Staff #34 confirmed the findings.</p> <p>Review of the facility provided work orders did not reflect the condensation in the dish room had been reported but did reflect the draining in the pot area had been reported as follows:</p> <p>#2838298 on 3/11/19 at 10:42 am, "water leaking from ceiling in the Pot Area STAT."</p> <p>#2830138 on 3/5/19 submitted at 2:08 pm, "ceiling leaking water in the pot area! Can someone assist immediately!!! Thanks." Maintenance responded on 3/5/19 at 2:15 pm.</p> <p>#2754939 on 1/24/19, "THE CEILING TILE IN THE DISHROOM HAS MOLD GROWING AND NEED TO BE REPLACE - CMS EOC"</p> <p>C.) Review of the facility's contract between Sodexo and the Facility reflected, "CHI facility shall provide all such safety equipment as may be reasonably necessary for safe performance of the Program (including, but not limited to... monitoring equipment...) 3.2 Make such improvements and/or alterations to the facilities as it may deem</p> | A 619 | | | |

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| A 619 | <p>Continued From page 117</p> <p>necessary or to comply with federal, state, or local laws. Maintain and repair the building structures in the area assigned for the Programs' use including painting and redecorating, maintenance of water, steam and sewer, electrical lines, grease traps, ventilation... floor coverings, walls and ceilings.... 3.10 Provide contracted services for equipment repair and preventive maintenance...."</p> <p>Review of the facility work orders related to Water backing up in kitchen from 1/8/19 to 3/25/19 reflected,</p> <p>#2731604 on 1/8/19 at 6:56 am, "Water is coming out from under the steam table and causing a slip hazard. ASAP."</p> <p>#2757845 on 1/26/19 at 10:14 pm, "there is a water build up due to the dish machine."</p> <p>#2756847 on 1/26/19 at 10:22 am, "I have a drain stop up under the dishwasher and water is flooding the floor in the dish room. Can you please come now please. Thanks!"</p> <p>#278455 on 2/8/19 at 8:02 am, "under the dish machine is not draining properly and water is all the floor."</p> <p>#2784451 on 2/8/19 at 8:01 am, "WE have emergency we have the drains backing up in the kitchen."</p> <p>#2784450 on 2/8/19 at 8:00 am, "drain in the cooks [sic] area is plug."</p> <p>#2788906 on 2/11/19 at 7:31 pm, "one of the</p> | A 619 | | | |

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| A 619 | <p>Continued From page 118</p> <p>drains is clogged and is backed up in the kitchen area. It is overflowing with water."</p> <p>#2788905 on 2/11/19 at 7:29 pm, "floor drain is clogged need assistance ASAP!!!!!"</p> <p>#2788709 on 2/11/19 on 15:25 pm, "clogged drain on ice machine, on line B."</p> <p>#2802458 on 2/21/19 at 7:58 am, "Potwashing [sic] Station in kitchen ... Floor drain is plugged up."</p> <p>#2801533 on 2/20/19 at 1:35 pm, "floor drain clogged in pot area need assistance A.S.A.P. please and thanks!"</p> <p>#2799307 on 2/19/19 at 7:52 am, "Sewer gas smell inside hallway on floor B1, particularly near Food Service all the way to the Paint shop."</p> <p>#2796828 on 2/17/19 at 9:18 pm, "The drainage under the Hobart dish machine is stopped up. Large puddles of water is in the dishroom [sic] mainly in the back of the dish room."</p> <p>#2811844 on 2/27/19 at 4:58 pm, "foul smell coming from drain in cafeteria can someone please come check on it A.S.A.P."</p> <p>#2835826 on 3/9/19 at 7:33 am, "Grease trap on the tray line is leaking onto the floor."</p> <p>#2838298 on 3/11/19 at 10:42 am, "water leaking from ceiling in the Pot Area STAT."</p> <p>#2841684 on 3/12/19 at 8:05 pm, "3 Clogged and Dirty drains next to hood fire extinguishing control panel. They need to be cleaned out and</p> | A 619 | | | |

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| A 619 | <p>Continued From page 119</p> <p>unclogged please. They are the square drains on the right side of the kitchen."</p> <p>#2849484 on 3/18/19 at 10:39 am, "Flush all floor drains with citrus cleaner. Entire kitchen smells of sewer smell right now."</p> <p>#2849177 on 3/18/19 at 7:47 am, "The sewage is backing up on hotline."</p> <p>#2849166 on 3/18/19 at 7:41 am, "Drain clogged in kitchen."</p> <p>#2848011 on 3/17/19 at 3:07 pm, "Kitchen drains in foodcourt[sic] backing up."</p> <p>Observations on the mornings of 3/25/19 and 3/27/19 revealed a foul odor coming from the drains. There was no observable water backing-up at these times.</p> <p>During an interview on 3/28/19, when asked about the repeated entries of the work orders on 2/8/19, 2/11/19, and 3/18/19, Staff #24, stated, "... I try to convey the urgency... I say please and thanks, what ever it takes...."</p> <p>During an interview on 3/28/19, in the administrative office, when asked about the sewer drains backing up in the kitchen Staff #118 stated, "...We did an assessment of the building years ago... it's an old system.... We wait until the kitchen puts in a work order...." Staff #118 confirmed preventative measures and monitoring of the drains were not in place.</p> <p>During an interview on 3/30/19, in the facility's kitchen, Staff #35 stated, "... We weren't aware of</p> | A 619 | | | |

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| A 619 | <p>Continued From page 120 the drains backing-up.... "</p> <p>D.) Review of the facility provided policy Sanitation Program (dated 2/7/19) reflected, "...Purpose: To maintain a clean safe and effective environment of care, and to prevent the transmission of disease-carrying organisms. PROCEDURES:</p> <ol style="list-style-type: none"> 1. The Sodexo General Manager monitors sanitizing schedules and procedures. Equipment, wall, floors and storage areas are routinely cleaned with appropriate sanitizing compounds. 2. Local and State sanitation requirements are reflected in schedules, procedures and sanitizing compounds in use. 3. Sodexo Food Safety Audits and Sanitation Self-Inspections are conducted per Sodexo HACCP standards to monitor the effectiveness of the Sanitation Program...." <p>Observations on the morning of 3/25/19, in the facility's Food Services Department revealed,</p> <ul style="list-style-type: none"> - Food debris and cranberry juice was stuck on the outside and on the inside of the ice machine the next day, in spite of the facility cleaning it on the first day, the debris and juice was still present. - (6) drains had food debris and a dark, gray slimy residue inside the drain; a foul smell was coming from the drains. - A large area of dark brown dried liquid was pooled on the bottom of a food holding cabinet. | A 619 | | | |

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| A 619 | <p>Continued From page 121</p> <ul style="list-style-type: none"> - Dried food debris was stuck on the cooking utensils and was available for use. There was dried food debris on the bottom of the utensil's cabinet drawers. - The food processor and buffalo chopper had multiple chips in the metal bowl, making it difficult to clean and placing patients at risk of ingesting metal shavings. - (19) out of (19) metal food trays were stored wet and with food debris left on the cooking surfaces and were available for use. - A box of edible orchids, that require refrigeration were sitting on a hot shelf out of refrigeration. - The food cutting mat had gouges (making it difficult to clean) and dried food debris stuck to them and was stored away and available for use. - Chicken strips, vegetable oil, fries and tortilla chips were not labeled and dated when opened. - Trays for utensils contained dry food debris. - A sanitizer bucket requiring a Quaternary Ammonia level of 200, registered 0 (preventing adequate sanitizing of food preparation areas) and two sanitizer buckets were registering 500, (allowing chemical residue to be transferred to the patient's foods). - The sides of the tilt skillets were coated with grease and food build-up two days in a row, in spite of the facility's attempt to cleaning it on the first day. | | | A 619 | | | |

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| A 619 | <p>Continued From page 122</p> <ul style="list-style-type: none"> - Raw bell peppers and lemons had mold growth and were available for use. - The two manual can openers had metal shavings scattered at the base of the holsters, placing patients at risk of ingesting the metal shavings and contaminates and one had food particles on the cutting blade and gear. - The floor had copious amounts of dried grease and food particles in the grout lines throughout the kitchen and behind the stove and grill creating an environment for bacterial growth. - (45) Metal food holding pans were being stored wet and stacked on top of each other creating an optimal environment for bacterial growth. <p>Review of the contract between Sodexo and the Facility reflected, ".... Gold Check Audits. Are performed at least semiannually for each CHI Facility to ensure compliance with program operating standards: The audits will be conducted by a minimum of two individuals, a Sodexo Account Executive or designee and a CHI Facility leader as designated by CHI or the Program.... Should a CHI Facility fail to achieve a score of at least 80% or higher, quarterly audits will be performed until a score of at least 80% is achieved.... A food safety audit will be conducted on a monthly basis by Program designee. The targeted score is greater than 90%, and a performance improvement plan will be developed for all areas not meeting standard"</p> <p>Review of the facility Monthly Food Safety Audit</p> | A 619 | | | |

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| A 619 | Continued From page 123 for February 2019, completed by the Sodexo staff, reflected a score of 75% and had only conducted one Gold Check Audit in 2018. The Gold Check audit was not conducted with a CHI Facility leader as the contract required. Review of the Sodexo provided SoSafe Food Safety Standards reflected, "...Refrigeration equipment maintained at 40 degrees Fahrenheit ... No evidence of contamination from raw foods of an animal origin or environmental sources (i.e. leakage, condensation, debris, glass, etc.)... Cutting boards in good condition (without cracks, deep grooves and discoloration) ...Cleaning Non-food Contact Surface... all non-food contact surfaces, under Sodexo responsibility (including cooking equipment, ... floors, floor mats, baseboards, wall, ceiling and exhaust fans or vent, etc.) clean ... Pot sink, storage carts and storage shelving clean and in good repair... Facility Cleaning Schedule specifying the equipment/location, designated personnel, and frequency on file...." | A 619 | | | |
| A 700 | PHYSICAL ENVIRONMENT CFR(s): 482.41 The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, | A 700 | | | |

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| A 700 | <p>Continued From page 124</p> <p>and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. This CONDITION is not met as evidenced by: Based on observations, interview, and record review, the facility failed to:</p> <p>A.) Maintain a safe physical environment when it failed to provide a sustainable correction for the kitchen's sewage drains that had been routinely backing up into the patient food production areas, placing patients at risk of consuming contaminated foods.</p> <p>B.) Ensure that ongoing maintenance inspections to identify areas in need of repair were conducted throughout the hospital environment. This failure resulted in environmental rounds not being conducted in 7 of 7 months (September 2018 through March 2019).</p> <p>C.) Have a secure power strip for the use on movable equipment in 1 of 1 Cath Lab procedure rooms. OR 6 and OR 11 (Fannin location) also had electrical extension/adapters with exposed wires plugged into the outlet. The facility also failed to monitor the temperature of the blanket warmer to reduce the risk of thermal burns.</p> <p>Refer to A0701</p> <p>D.) Ensure that equipment was stored/maintained in a manner that prevented potential contamination with cytotoxic drugs (compounds used to destroy cancer cells during chemotherapy) along with developing appropriate processes for cleaning equipment after contamination; and failed to ensure that</p> | A 700 | | | |

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| A 700 | Continued From page 125 departments only ordered the appropriate spill kits for cleaning cytotoxic spills in 1 (Kirby Glen Outpatient area) of 2 areas toured that administered chemotherapy. | A 700 | | | |
| A 701 | Refer to A0724 MAINTENANCE OF PHYSICAL PLANT CFR(s): 482.41(a) The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This STANDARD is not met as evidenced by: Based on observations, interview, and record review, the facility failed to: A.) Maintain a safe physical environment when it failed to provide a sustainable correction for the kitchen's sewage drains that had been routinely backing up into the patient food production areas. B.) Ensure that ongoing maintenance inspections to identify areas in need of repair were conducted throughout the hospital environment. This failure resulted in environmental rounds not being conducted in 7 of 7 months (September 2018 through March 2019). C.) Have a secure power strip for the use on movable equipment in 1 of 1 Cath Lab procedure rooms. OR 6 and OR 11(Fannin location) also had electrical extension/adapters with exposed wires plugged into the outlet. The facility also failed to monitor the temperature of the blanket warmer to reduce the risk of thermal burns. Findings: | A 701 | | | |

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| A 701 | <p>Continued From page 126</p> <p>A.) Review of the contract between Sodexo and the Facility reflected, "CHI facility shall provide all such safety equipment as may be reasonably necessary for safe performance of the Program (including, but not limited to... monitoring equipment...) 3.2 Make such improvements and/or alterations to the facilities as it may deem necessary or to comply with federal, state, or local laws. Maintain and repair the building structures in the area assigned for the Programs' use including painting and redecorating, maintenance of water, steam and sewer, electrical lines, grease traps, ventilation... floor coverings, walls and ceilings.... 3.10 Provide contracted services for equipment repair and preventive maintenance...."</p> <p>Review of the facility provided Water backing up in kitchen work orders from 1/8/19 to 3/25/19 reflected,</p> <p>#2731604 on 1/8/19 at 6:56 am, "Water is coming out from under the steam table and causing a slip hazard. ASAP."</p> <p>#2757845 on 1/26/19 at 10:14 pm, "there is a water build up due to the dish machine."</p> <p>#2756847 on 1/26/19 at 10:22 am, "I have a drain stop up under the dishwasher and water is flooding the floor in the dish room. Can you please come now please. Thanks!"</p> <p>#278455 on 2/8/19 at 8:02 am, "under the dish machine is not draining properly and water is all the floor."</p> <p>#2784451 on 2/8/19 at 8:01 am, "WE have</p> | A 701 | | | |

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| A 701 | <p>Continued From page 127</p> <p>emergency we have the drains backing up in the kitchen."</p> <p>#2784450 on 2/8/19 at 8:00 am, "drain in the cooks [sic] area is plug."</p> <p>#2788906 on 2/11/19 at 7:31 pm, "one of the drains is clogged and is backed up in the kitchen area. It is overflowing with water."</p> <p>#2788905 on 2/11/19 at 7:29 pm, "floor drain is clogged need assistance ASAP!!!!!"</p> <p>#2788709 on 2/11/19 on 15:25 pm, "clogged drain on ice machine, on line B."</p> <p>#2802458 on 2/21/19 at 7:58 am, "Potwashing [sic] Station in kitchen ... Floor drain is plugged up."</p> <p>#2801533 on 2/20/19 at 1:35 pm, "floor drain clogged in pot area need assistance A.S.A.P. please and thanks!"</p> <p>#2799307 on 2/19/19 at 7:52 am, "Sewer gas smell inside hallway on floor B1, particularly near Food Service all the way to the Paint shop."</p> <p>#2796828 on 2/17/19 at 9:18 pm, "The drainage under the Hobart dish machine is stopped up. Large puddles of water is in the dishroom [sic] mainly in the back of the dish room."</p> <p>#2811844 on 2/27/19 at 4:58 pm, "foul smell coming from drain in cafeteria can someone please come check on it A.S.A.P."</p> <p>#2835826 on 3/9/19 at 7:33 am, "Grease trap on the tray line is leaking onto the floor."</p> | A 701 | | | |

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| A 701 | <p>Continued From page 128</p> <p>#2838298 on 3/11/19 at 10:42 am, "water leaking from ceiling in the Pot Area STAT."</p> <p>#2841684 on 3/12/19 at 8:05 pm, "3 Clogged and Dirty drains next to hood fire extinguishing control panel. They need to be cleaned out and unclogged please. They are the square drains on the right side of the kitchen."</p> <p>#2849484 on 3/18/19 at 10:39 am, "Flush all floor drains with citrus cleaner. Entire kitchen smells of sewer smell right now."</p> <p>#2849177 on 3/18/19 at 7:47 am, "The sewage is backing up on hotline."</p> <p>#2849166 on 3/18/19 at 7:41 am, "Drain clogged in kitchen."</p> <p>#2848011 on 3/17/19 at 3:07 pm, "Kitchen drains in foodcourt[sic] backing up."</p> <p>Observations on the mornings of 4/25/19 and 4/27/19 revealed a foul odor coming from the drains; there was no observable water backing-up at these times.</p> <p>During an interview on 3/28/19, when asked about the repeated entries of the work orders on 2/8/19, 2/11/19, and 3/18/19 Staff #24, stated, "... I try to convey the urgency... I say please and thanks, what ever it takes...."</p> <p>During an interview on 3/28/19, in the administrative office, when asked about the the sewer drains backing up in the kitchen Staff #118 stated, "...We did an assessment of the building</p> | A 701 | | | |

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| A 701 | <p>Continued From page 129</p> <p>years ago... it's an old system.... We wait until the kitchen puts in a work order...." Staff #118 confirmed preventative measures and monitoring of the drains were not in place.</p> <p>During an interview on 3/30/19, in the facility's kitchen, Staff #35 stated, "... We weren't aware of the drains backing-up.... "</p> <p>B.) Record review of the document titled, Safety Management Plan, effective date January 2019, showed: " ... PE (Physical Environment) Rounds ...</p> <p>2.02 - The physical environment is observed during Environment of Care (EOC) Rounds. EOC Rounds are conducted periodically throughout the hospital and may become more focused on areas or issues that Safety Services, the Manager of Safety, or the Workplace Safety Subcommittee deems as higher-risk ... "</p> <p>Record review of the document titled, Life Safety Management Plan, effective date January 2019, showed: " ... 7.00 - Measuring and Improving Activities. Conditions in the environment are monitored to identify discrepancies and improve the safety and reliability of systems and processes ... 7.03 - The Hospital Safety Officer, the Environment of Care Committee (EOCC), and the EOCC Sub-committees have established and implemented a process for ongoing monitoring of actual or potential risks in each of the management plans."</p> <p>Record review of the document titled, 2018 Environment of Care Rounds Update, dated 08/14/2018, showed data collected from the EOC</p> | A 701 | | | |

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| A 701 | <p>Continued From page 130 rounds.</p> <p>Record review of the document titled, 2019 Environment of Care Rounds [schedule], showed Round One and Round Two. (There was no date specified on the document.) Round One are scheduled to begin 04/01/2019 and conclude 09/16/2019. Round Two was scheduled to begin 09/02/2019 and end 12/09/2019.</p> <p>In an interview with Staff #154 on 03/29/2019 at 9:30 AM, he stated that:</p> <p>The Environment of Care rounds are supposed to be completed once a year with specific areas of the hospital being done monthly; thus, at the end of the year, all areas of the hospital are evaluated; and</p> <p>The Environment of Care rounds had not been conducted since August, 2018, adding that these rounds should have occurred each month.</p> <p>C.) There was an unsecured power strip cord lying on the bottom shelf of a small metal cart holding the defibrillator. The electrical cords were running across the floor in the Cath Lab procedure room #10 next to an IV pole. The power strip outlet had two power cords plugged into it.</p> <p>A review of the NFPA 99 guidelines revealed the following:</p> <p>"Use of extension cords in Operating Rooms: The code states that the power cord from the device must be "continuous and without switches from appliance to the attachment plug" (NFPA 99 7-5.1.2.5). This has been interpreted as</p> | A 701 | | | |

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| A 701 | <p>Continued From page 131</p> <p>forbidding extension cords in anesthetizing locations. The only exception is a permanently mounted power cord on a movable equipment assembly on a rack or table."</p> <p>In an interview with RN #177 on 4/1/2019 at 9:49 AM, confirmed the power strip outlet cords were laying on the metal cart unsecured and across the procedure floor.</p> <p>During a tour on March 26, 2019 after 10:00 AM the following observations were noted:</p> <p>FANNIN SURGERY</p> <p>OR 6</p> <p>There was an electrical extension/adaptor with exposed electrical wires plugged into the wall outlet. There was an electrical cord plugged into it.</p> <p>OR 11</p> <p>There was an electrical extension/adaptor with exposed electrical wires plugged into the wall outlet. There was an electrical cord plugged into it.</p> <p>During a tour on April 1, 2019 after 8:30 AM the following observation was made:</p> <p>CATH LAB</p> <p>There was a blanket warmer in the hallway. There were blankets stored in the warmer. RN #178 was asked if the blankets were used on patients. RN #178 confirmed they were. RN #178 said, the staff did check the temperature on the blankets visually, but they did not have a log in the department where the temperature was</p> | A 701 | | | |

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| A 701 | <p>Continued From page 132</p> <p>documented. There was no other documentation to show that the temperature for the warmer was monitored daily.</p> <p>Review of the AORN (Association of periOperative Registered Nurses) guidelines for PeriOperative Practice: Environment of Care revealed the following:</p> <p>"VI. Perioperative personnel should take precautions to reduce the risk for thermal injuries related to warming solutions, blankets, and linens in blanket and solution-warming cabinets.</p> <p>The danger of burns from heated solutions, blankets, or linens is increased in the perioperative setting because patients may be unconscious or sedated and not able to feel an increase in temperature or communicate discomfort. Even when solutions and blankets do not feel warm to the touch, heat continues to build in these items and can be transferred to the patient.</p> <p>Injuries to the patient can result from irrigation solution being warmed to high temperatures. In one report, a patient experienced full-thickness skin burns and joint damage from irrigation solutions that were warmed in a cabinet in which the temperature ranged from 100.4° F (38° C) on the top shelf to 118.4° F (48° C) on the bottom shelf</p> <p>VI.b Warming cabinet temperatures should be set, maintained, and monitored according to organizational policy.</p> <p>Monitoring the temperature of warming cabinets is necessary to verify that temperature settings are maintained within specified limits. A</p> | A 701 | | | |

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| A 701 | Continued From page 133 malfunctioning cabinet can cause temperature variation... | A 701 | | | |
| A 724 | <p>VI.d. An interdisciplinary team should conduct a risk assessment to establish and implement a maximum temperature limit for blanket-warming cabinets based on evidence and the cabinet manufacturer's IFU."</p> <p>FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE CFR(s): 482.41(d)(2)</p> <p>Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This STANDARD is not met as evidenced by: Based on review of records, observations, and interview, the facility failed to ensure that equipment was stored/maintained in a manner that prevented potential contamination with cytotoxic drugs (compounds used to destroy cancer cells during chemotherapy) along with developing appropriate processes for cleaning equipment after contamination; and failed to ensure that departments only ordered the appropriate spill kits for cleaning cytotoxic spills in 1 (Kirby Glen Outpatient area) of 2 areas toured that administered chemotherapy.</p> <p>On 3-27-2019, at approximately 9:30 AM, a tour of the Kirby Glen outpatient infusion area was conducted with Staff #167 and RN #115. The hazardous waste storage room was observed. This room was used to store chemotherapy waste and biohazardous waste. A bedside commode was observed to be stored in the room with the hazardous waste. The commode was observed to be of a large size to accommodate</p> | A 724 | | | |

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| A 724 | <p>Continued From page 134</p> <p>obese patients. Staff #167 stated, it was kept in this room because space was limited and this was the only space available. The commode was observed to have a wooden dowel with an open roll of toilet paper attached to the right arm of the chair. Staff #167 was asked if this bedside commode was for patient use. Staff #167 replied that it was not clean and that staff would clean the bedside commode prior to use.</p> <p>RN #115 was interviewed at approximately 9:45 AM on the proper technique for cleaning the bedside commode. RN #115 stated she take the commode just outside of the hazardous waste storage room and wipe the commode down with germicidal disposable wipes. She would ensure the commode was damp for the 2 minutes required to ensure the germicide was effective. RN #115 stated, the commode would then be provided to the patient for use.</p> <p>This process did not decontaminate the commode in the event that it had been unknowingly exposed to chemotherapy waste during the storage process. The toilet paper and wooden dowel it was hanging from could not be decontaminated or disinfected if exposed to chemotherapy or biohazard waste during the storage process since these materials were porous.</p> <p>Staff #167 stated, she thought germicidal wipes were appropriate for cleaning the commode since they were in the Chemotherapy Spill Kits used to contain and clean chemotherapy spills. Spill kits were observed to be readily available in the supply storage area. The spill kit label was as follows:</p> | A 724 | | | |

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| A 724 | <p>Continued From page 135</p> <p>"Basic Chemo Spill Kit Item number KIT-SW</p> <p>Contents: 1 ea Chemo-Wipe Bag (Trademark) 1 ea Fluid Impervious Gown 3 ea Absorbent Towelettes 1 pr Chemo-Nitrile Gloves 1 ea Fluid Impermeable Mask w/ Safety Shield 1 ea Yellow Chemo Waste Bag w/Twist Tie 1 ea Hard Surface Disinfectant Wipe 1 ea Antimicrobial Hand Towelette 1 ea Set of Instructions In English and Spanish</p> <p>Kit Expiration Date: April 2020</p> <p>The kit did not contain any markings stating that it was an Occupational Safety and Health Administration (OSHA) approved chemotherapy spill kit and was lacking supplies necessary to be OSHA approved.</p> <p>Review of OSHA's website, https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html ; Controlling Occupational Exposure to Hazardous Drugs, showed that spill kits were recommended to contain the following under V. Prevention of Employee Exposure, H. Spills:</p> <p>"2. Spill Kits. Spill kits containing all of the materials needed to clean up spills of HDs should be assembled or purchased (ASHP, 2006). These kits should be clearly labeled, should be kept in or near HD preparation and administrative areas, as well as HD receiving and storage areas where spills may occur. Spill kits should be located on HD transport carts and staff transporting HDs should be trained to manage a</p> | A 724 | | | |

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| A 724 | <p>Continued From page 136</p> <p>spill (ASHP, 2006). The HD-specific SDS should include sections on emergency procedures, including appropriate personal protective equipment.</p> <p>The ASHP recommends that kits include (ASHP, 2006):</p> <p>a.Sufficient supplies to absorb a spill of about 1000mL (volume of one IV bag or bottle).</p> <p>b.Appropriate PPE to protect the worker during cleanup, including two pairs of disposable chemotherapy gloves, non-permeable, disposable protective garments (coveralls or gown and shoe covers), and face shield.</p> <p>c.Absorbent, plastic-backed sheets or spill pads.</p> <p>d.Disposable toweling.</p> <p>e.At least two sealable, thick plastic hazardous waste disposal bags (pre-labeled with an appropriate warning label).</p> <p>f.One disposable scoop for collecting glass fragments.</p> <p>g.One puncture-resistant container for glass fragments.</p> <p>In addition, NIOSH recommends eye and face protection and a full-face piece chemical cartridge-type respirator for events such as large spills (NIOSH, 2005; NIOSH, 2009). Respirators should be available near the spill kits.</p> <p>Prior to cleanup, appropriate protective</p> | A 724 | | | |

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| A 724 | <p>Continued From page 137</p> <p>equipment should be donned. Absorbent sheets should be incinerable. Reusable protective eye/face gear and respirators should be cleaned with mild detergent and water after use. Items contaminated with HDs should be washed three times with detergent by a trained employee wearing personal protective equipment as described in the PPE section (NIOSH, 2004; Polovich, 2011)."</p> <p>Review of Policy and Procedure Title: Handling and Disposal of Hazardous Materials, Maintained by: Hospital Safety Officer, Reviewed by: Infection Control, Radiation Safety, and Environmental Services, Effective date: February 2019, was made. A section containing specific procedures for managing cytotoxic spills was found. No evidence was found that Pharmacy was included in the review and development of procedures for the management of chemotherapy medication spills (cytotoxic agents). Review of item 2. Selection and Purchase of Hazardous Chemicals, b., iv., stated, "The appropriate applicable Personal Protection Equipment (PPE), spill kits, storage containers, labels and warning signs must be purchased by the department."</p> <p>An interview was conducted with the Safety Officer, Staff #154, on the afternoon of 3-28-2019. Staff #154 confirmed that each department was responsible for ordering their own kits and that the hospital did not have a process in place to prevent the ordering and use of kits that were not OSHA approved.</p> <p>Staff #154 was asked about the procedures for cleaning equipment, such as the bedside commode, after coming in contact with chemotherapy drugs. Staff #154 stated that he</p> | A 724 | | | |

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| A 724 | Continued From page 138 believed all chemotherapy agents to be water soluble so that they could be safely cleaned and deactivated with water. Per the policy, Handling and Disposal of Hazardous Materials, specific procedures for Cytotoxic Spills included: "Small spills, those less than 50ml, may be absorbed with paper towels and the area rinsed with an equal amount of water. Gloves must be worn." Staff #154 was asked to provide the standards or guidelines being referenced for that procedure, such as OSHA or the Material Safety Data Sheets, showing that this was a safe and effective process for cleaning and deactivating spills of hazardous drugs like chemotherapy. No such reference was provided. | A 724 | | | |
| A 747 | INFECTION CONTROL CFR(s): 482.42 The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observations, interviews, and records review, the facility failed to provide a sanitary environment to avoid sources and transmission of infectious and communicable diseases. The facility failed to: A.) Ensure nursing staff followed nationally accepted standards of infection control measures by appropriately applying and/or removing | A 747 | | | |

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| A 747 | <p>Continued From page 139</p> <p>Personal Protective Equipment (PPE) when working in isolation rooms, disinfected mobile computer carts (WOW) and portable equipment, as well as provided patient and family education regarding isolation precautions.</p> <p>B.) Ensure that staff disinfected transvaginal ultrasound transducers between patients and maintained the sterile field in sterile pharmaceutical compounding areas.</p> <p>C.) Ensure the sterility of the compounding area of the pharmacy.</p> <p>D.) Ensure procedure rooms and patient rooms were terminally cleaned following use by patients with the likelihood of infectious disease.</p> <p>E.) Ensure Environmental Services/Housekeeping maintained isolation precautions to prevent cross contamination while conducting housekeeping services.</p> <p>These deficient practices were determined to pose an Immediate Jeopardy to patient health and safety, and placed all patients at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>F.) Ensure staff observed standard precautions during the provision of hemodialysis care.</p> <p>G.) Ensure the walk-in refrigerator #68, which contained the milk products used for the patients, maintained appropriate temperatures.</p> <p>H.) Ensure that the facility's two large mechanical dish washers, which were building up copious</p> | A 747 | | | |

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| NAME OF PROVIDER OR SUPPLIER CHI ST LUKE'S HEALTH BAYLOR COLLEGE OF MEDICINE ME | | | STREET ADDRESS, CITY, STATE, ZIP CODE 6720 BERTNER HOUSTON, TX 77030 | | |
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| A 747 | <p>Continued From page 140</p> <p>amounts of steam that was condensing and dripping off the dirty ceiling tiles onto the cleaned dishware, were repaired and the contaminated dishware were not utilized.</p> <p>I.) Ensure that the facility kitchen's sewer drains, which were repeatedly backing up throughout the kitchen food preparation areas, were repaired and maintained in working order.</p> <p>Refer to Tag A 619</p> <p>J.) Know the Hepatitis B antibody status or administer the immunization for non-immune staff for 3 (#77, #78, and #194) of 10 surgical staff health records reviewed. Also, the facility failed to follow their policy on Hepatitis B monitoring and follow-up guidance. Also, the facility failed to follow the CDC guidelines.</p> <p>K.) Know the Tuberculosis status for 1 (#78) of 10 surgical staff health records reviewed. Also, the facility failed to follow their policy on Tuberculosis monitoring and follow-up guidance.</p> <p>L.) Monitor the expiration dates of the Rapicide strips used to check the concentration level of the peri-acetic acid during high level disinfection. The facility also failed to clean or change the filter on the Jun-Air compressor in the endoscope reprocessing room.</p> <p>M.) Ensure a clean and sanitary environment in the facility-wide Surgical Department.</p> <p>N.) Ensure a clean and sanitary environment hospital wide and off-site locations.</p> | A 747 | | | |

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| A 747 | Continued From page 141 | A 747 | | | |
| A 749 | Refer to Tag A 0749 INFECTION CONTROL PROGRAM CFR(s): 482.42(a)(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: Based on observations, interviews, and records review, the facility failed to provide a sanitary environment to avoid sources and transmission of infectious and communicable diseases. The facility failed to: A.) Ensure nursing staff followed nationally accepted standards of infection control measures by appropriately applying and/or removing Personal Protective Equipment (PPE) when working in isolation rooms, disinfected mobile computer carts (WOW) and portable equipment, as well as provided patient and family education regarding isolation precautions. B.) Ensure that staff disinfected transvaginal ultrasound transducers between patients and maintained the sterile field in sterile pharmaceutical compounding areas. C.) Ensure the sterility of the compounding area of the pharmacy. D.) Ensure procedure rooms and patient rooms were terminally cleaned following use by patients with the likelihood of infectious disease. | A 749 | | | |

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| A 749 | <p>Continued From page 142</p> <p>E.) Ensure Environmental Services/Housekeeping maintained isolation precautions to prevent cross contamination while conducting housekeeping services.</p> <p>These deficient practices were determined to pose an Immediate Jeopardy to patient health and safety, and placed all patients at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>F.) Ensure staff observed standard precautions during the provision of hemodialysis care.</p> <p>G.) Know the Hepatitis B antibody status or administer the immunization for non-immune staff for 3 (#77, #78, and #194) of 10 surgical staff health records reviewed. Also, the facility failed to follow their policy on Hepatitis B monitoring and follow-up guidance. Also, the facility failed to follow the CDC guidelines.</p> <p>H.) know the Tuberculosis status for 1 (#78) of 10 surgical staff health records reviewed. Also, the facility failed to follow their policy on Tuberculosis monitoring and follow-up guidance.</p> <p>I.) Monitor the expiration dates of the Rapicide strips used to check the concentration level of the periacetic acid during high level disinfection. The facility also failed to clean or change the filter on the Jun-Air compressor in the endoscope reprocessing room.</p> <p>J.) Ensure a clean and sanitary environment in the facility-wide Surgical Department.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 143</p> <p>K.) Ensure a clean and sanitary environment hospital wide and off-site locations.</p> <p>This deficient practice placed all patients receiving treatment in the facility at an increased risk of life threatening infections, leading up to and including the possibility of death.</p> <p>Findings:</p> <p>A.) Observations conducted on 3/25/19 from 9:30 am to 2:30 pm, with Infection Control Preventionist #14 revealed the following:</p> <p>Patient# 83:</p> <p>A sign was located on Patient#83's room door which stated the patient was on contact isolation precautions. Staff #91 was observed in the patient room speaking on a cordless phone, holding the cordless phone up to her face (in contact with skin) while wearing soiled gloves. A rolling computer cart (WOW) was also observed in the room. Upon continued observation, the nursing staff cleaned the cordless phone using an alcohol prep pad, then placed the phone on top of the computer cart, which was not cleaned/ disinfected. Nursing staff then left the isolation room.</p> <p>In an interview conducted on 3/25/19, at the time of observation, Infection Control Preventionist #14 confirmed that Staff #91 was not following standard infection control procedure in the disinfection of portable equipment. He further revealed that nursing staff were to be using the "purple top" Sani-cloth disinfectant to clean</p> | A 749 | | | |

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| A 749 | <p>Continued From page 144 equipment.</p> <p>Record review of the facility medical record for patient#83 revealed that he was a 44-year-old male, admitted to the facility on 3/14/19, with diagnosis of: Fever, lethargy, S/P implantation of Left Ventricular Assistive Device (LVAD), chronic respiratory failure, Diabetes Mellitus Type II and ESRD. Further review revealed that he was on isolation precautions for Methicillin-resistant Staphylococcus Aureus (MRSA).</p> <p>Record review of the facility policy entitled "Standard and Transmission Based Precautions", dated 03/05/2015, revealed in part the following information:</p> <p>"i.) Equipment use, Environmental Cleaning, and Patient Procedures:</p> <p>1.) Provide patient with his or her own equipment. This includes, but is not limited to, electronic thermometer, blood pressure cuff, manometer, slings, stethoscope, IV pole, etc. Non-critical portable patient care equipment for patients on isolation can be disinfected with hospital-approved disinfectant. Exception: Equipment used on patients on Enteric Contact Precautions for C-Diff will be disinfected with a hospital-approved sporicidal disinfectant.</p> <p>Patient #14</p> <p>Observations conducted on 3/25/19, between 9:30 am to 2:30 pm revealed the following:</p> <p>A sign was located on patient#14's room door which stated the patient was on contact isolation</p> | A 749 | | | |

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| A 749 | <p>Continued From page 145</p> <p>precautions. A portable reverse osmosis (RO) machine, used for hemodialysis, was located in the hallway outside of Patient# 14's room.</p> <p>In an interview conducted on 3/25/19, at the time of discovery, Staff#3 revealed that housekeeping staff had removed the RO machine out of the isolation room. Staff #3 stated that he did not know if the machine was clean or dirty, and/or was disinfected prior to being removed from the isolation room.</p> <p>In an interview conducted on 3/25/19 at 10:15am, the RN Unit Manager was asked by the surveyor if the portable RO machine located in the common hallway, which was removed from Patient#14's isolation room, had been disinfected prior to removal. The unit manager stated that she did not know if the machine was "clean" or "dirty".</p> <p>Continued observations conducted on 3/26/19 between 9:00am -11:00 am, of Patient#14 revealed the following:</p> <p>Patient#14 remained on contact isolation precautions. The patient was noted to have a tracheostomy and was on 28% oxygen via trach collar. Staff #32 was observed at the bedside, and began to preform tracheostomy suctioning. Staff #32 was not wearing a face mask or face shield.</p> <p>In an interview conducted on 3/26/19, at the time of observation, Infection Preventionist #14 was asked by the surveyor what type of PPE was required when staff preformed tracheostomy suctioning in the isolation room. The Infection Preventionist stated that staff are only required to</p> | A 749 | | | |

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| A 749 | <p>Continued From page 146</p> <p>wear a gown and gloves, even when performing suctioning on a patient with an open tracheostomy.</p> <p>In an interview conducted on 4/01/19 at 10:05 am, the Environmental Services Manager (EVS) revealed that EVS staff do not disinfect medical equipment, and that disinfection of medical equipment was the responsibility of the nursing staff.</p> <p>Record review of the facility medical record for Patient#14 revealed that she was a 70-year-old female, admitted to the facility on 3/13/19 with diagnosis of: Chronic respiratory failure Status Post (S/P) tracheostomy and End Stage Renal Disease (ESRD). Further review revealed that she was on isolation precautions for Multi Drug resistant (MDR) pseudomonas of the sputum.</p> <p>Record review of the facility policy entitled "Standard and Transmission Based Precautions", dated 03/05/2015, revealed in part the following information:</p> <p>"Procedures:</p> <p>Standard Precautions:</p> <p>- h.) Masks, respiratory protection, eye protection, and face shields are worn alone, or in combination with other Personal Protective Equipment (PPE), and should be worn by employees to provide barrier protection during procedures and patient care practices that are likely to generate splashes or sprays of blood or other body substances into the mucous membranes of the eyes, nose, mouth, or non-intact skin of the face. Examples of splash</p> | A 749 | | | |

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| A 749 | <p>Continued From page 147</p> <p>producing procedures include, but is not limited to, wound irrigation, oral suctioning, intubation, and when caring for patients with open tracheostomies where there is potential for projectile secretions.</p> <p>Patient#16</p> <p>A sign was located on patient#16's room door which stated the patient was on contact isolation precautions. Staff#24 was observed at the bedside providing patient care. Patient#16's family member was also at the bedside and was not wearing any PPE.</p> <p>In an interview conducted on 3/25/19 at 10:42am, Staff#24 was asked by the surveyor if he had provided patient and family teaching regarding isolation precautions. Staff#24 revealed that he had not done any training with the patient or family.</p> <p>Patient#15:</p> <p>A sign was located on patient#15's room door which stated the patient was on droplet isolation precautions. Staff#47 was observed at the patient's bedside wearing gloves only. She was not wearing any other PPE. Staff#47 provided patient care, then left the room, pushing the mobile computer cart (WOW) with her personal stethoscope hanging from the handle, into the hallway. Staff#47 did not sanitize the WOW cart or her personal stethoscope.</p> <p>In an interview conducted on 3/26/19 at 9:40 am, Staff #47 stated that Patient #15 was on droplet</p> | A 749 | | | |

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| A 749 | <p>Continued From page 148</p> <p>isolation precautions for Flu. When asked by the surveyor what type of protective PPE was required for droplet precautions, Staff #47 stated droplet precautions required only a mask and proper handwashing. When asked why she was not wearing a mask and/or gown, Staff #47 revealed that it was up to the nurses what they wore in isolation rooms. When asked by the surveyor why she took her personal stethoscope and WOW cart into the isolation room, she further revealed that she did not have a disposable stethoscope, blood pressure cuff, or dedicated WOW cart for the isolation room.</p> <p>Record review of the facility medical record for patient#15 revealed that she was a 79-year-old female, admitted on 3/20/19, with diagnosis of: Shortness of breath, anemia, atrial fibrillation, coronary artery disease, congestive heart failure S/P pacemaker. Further review revealed that she was on isolation precautions for Flu.</p> <p>Record review of the facility policy entitled "Standard and Transmission Based Precautions", dated 03/05/2015, revealed in part the following information:</p> <p>2.) Transmission-Based Precautions:</p> <p>a.) All employees will continue to practice Standard Precautions including hand hygiene and respiratory hygiene for all patient contact in addition to transmission-based precautions.</p> <p>h.) Appropriate Personal Protective Equipment (PPE) for Transmission-based Precautions:</p> <p>ii.) PPE for Droplet Precautions:</p> | A 749 | | | |

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| A 749 | <p>Continued From page 149</p> <p>1.)A standard isolation mask should be worn by everyone upon entering the patient's room. Masks with face shields or goggles should be worn as part of Standard Precautions for procedures which may generate splashing or aerosols.</p> <p>2.)Gowns are indicated if soiling, blood or body fluid exposure is likely.</p> <p>3.)Gloves should be worn for direct contact with the patient. Remove gloves and discard in appropriate waste container upon leaving the room.</p> <p>4.)After leaving the patient's room, remove mask and discard in appropriate waste bag. Preform hand hygiene.</p> <p>5.)Continue to follow Standard Precautions.</p> <p>i.) Equipment use, Environmental Cleaning, and Patient Procedures:</p> <p>1.) Provide patient with his or her own equipment. This includes, but is not limited to, electronic thermometer, blood pressure cuff, manometer, slings, stethoscope, IV pole, etc. Non-critical portable patient care equipment for patients on isolation can be disinfected with hospital-approved disinfectant. Exception: Equipment used on patients on Enteric Contact Precautions for C-Diff will be disinfected with a hospital-approved sporicidal disinfectant.</p> <p>Patient#13:</p> <p>Observations conducted on 3/26/19, between</p> | A 749 | | | |

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| A 749 | <p>Continued From page 150</p> <p>9:00 am -11:00 am revealed the following:</p> <p>A sign was located on patient#13's room door which stated the patient was on contact isolation precautions. Staff #48 stated the patient was in isolation for necrotizing fasciitis. The unit manager was then asked by the surveyor if there was any computer equipment present and available in the isolation room for staff use. Staff#48 stated that the room has a dedicated WOW cart for staff use at the bedside. Upon inspection of the isolation room, there was no evidence of a WOW cart.</p> <p>In an interview conducted on 3/26/19 at 10:20 am, Staff#49 revealed that there was a dedicated WOW cart in Pt#13's isolation room. However, she did not know when the isolation WOW cart had been removed, where it was currently located, and/or if it had been disinfected prior to removal. She further stated that she thought that the unit secretary had removed the isolation WOW cart for repair.</p> <p>In an interview conducted on 3/26/19 at 10:28 am, the medical/ surgical Unit Secretary stated that she had not removed the WOW cart from Pt #13's isolation room, and did not know where the cart was located.</p> <p>In an interview conducted on 3/26/19 at 10:35 am, Staff#2 was asked if she had removed the WOW cart from Pt#13's isolation room. Staff#2 stated that she had not removed anything from the isolation room, and did not know who had removed the cart, if it had been disinfected, or when it had been removed.</p> <p>During continued observation of Pt#13's isolation</p> | A 749 | | | |

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| A 749 | <p>Continued From page 151</p> <p>room, on 3/26/19 at 10:42 am Informational Technology (IT) delivered a "clean" isolation WOW cart for Pt#13's isolation room, leaving the cart outside of the room in the hallway. Observation of the "clean" WOW cart revealed unidentified dust and debris located across the entire bottom of the "clean" WOW cart.</p> <p>In an interview conducted on 3/26/19 at 10:42 am, Infection Preventionist# 14 confirmed that the new isolation WOW cart was not appropriately cleaned prior to delivery by IT staff. He further revealed that the small isolation WOW carts are only used in isolation rooms, and that the new WOW cart had "most likely" been located in another isolation room prior to delivery by IT staff.</p> <p>Record review of the facility medical record for Patient#13 revealed that she was a 50-year-old female, who was admitted on 2/17/19 with a diagnosis of: Necrotizing fasciitis of the abdominal wall, Diabetes Mellitus Type II, and severe sepsis.</p> <p>Record review of the facility policy entitled "Standard and Transmission Based Precautions", dated 03/05/2015, revealed in part the following information:</p> <p>i.) Equipment use, Environmental Cleaning, and Patient Procedures:</p> <p>1.) Provide patient with his or her own equipment. This includes, but is not limited to, electronic thermometer, blood pressure cuff, manometer, slings, stethoscope, IV pole, etc. Non-critical portable patient care equipment for patients on isolation can be disinfected with hospital-approved disinfectant. Exception:</p> | A 749 | | | |

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| A 749 | <p>Continued From page 152</p> <p>Equipment used on patients on Enteric Contact Precautions for C-Diff will be disinfected with a hospital-approved sporicidal disinfectant.</p> <p>Observations conducted on 3/27/19 from 8:30 am to 10:45 am of the McNair campus revealed the following:</p> <p>-MRI Room: The room was marked as clean and ready for patient use. Observation of the MRI table revealed a clear liquid substance running down the side of the table and onto the floor. Observation of the floor revealed a dried white substance which looked like it had been dripped across the room to the counter area. Further observation of the floor underneath the MRI machine revealed an ace bandage, luer lock caps, as well as dust and debris were located underneath the machine.</p> <p>In an interview conducted on 3/27/19, at the time of discovery, Staff#121 confirmed that the MRI room had been cleaned and was ready for the next patient. When asked by the surveyor about the white substance on the floor, Staff#121 stated "I don't know what that is, but it won't come off the floor." The surveyor donned gloves and wiped the area with a disinfectant wipe, and the substance came off the floor. During further interview, Staff#121 revealed that radiology staff are responsible for cleaning the MRI room, to include the machine.</p> <p>B.) During continued observations conducted on 3/27/19 from 10:00 am to 10:45 am, of the McNair campus, revealed the following:</p> <p>-Ultrasound/ Sonography area: A Phillips ultra sound machine was observed, to include</p> | A 749 | | | |

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| A 749 | <p>Continued From page 153 standard and transvaginal transducers.</p> <p>In an interview conducted on 3/27/19 at 10:10 am, Staff#122 was asked by the surveyor how she was disinfecting the transvaginal transducers. She stated, "I just run them under the tap water and wipe them off with a paper towel." When asked if she was aware of the manufacture's recommendations for disinfecting the transvaginal transducers, and/or the facility's infection control policy regarding disinfection, the sonographer stated that she was not aware, nor had she been trained in the disinfection of the transvaginal transducers.</p> <p>Record review of the Phillips ultrasound manual, Undated, Pages 44-51, revealed in part the following information:</p> <p>Low level Disinfection of Non-TEE Transducers:</p> <p>1.) Clean the transducer and cable according to the procedures in "Cleaning Non-TEE Transducers, cables, and connectors."</p> <p>2.) After cleaning, choose low or intermediate level disinfectants that are compatible with your transducer, cable, and connector.</p> <p>3.) Wipe or spray the transducer, cable, strain relief, and connector with the disinfectant, following disinfectant label instructions for temperature, wipe durations, and duration of disinfectant contact</p> <p>4.) Air dry, or if necessary, use a soft cloth to dry the transducer. To dry the lens, use a blotting motion instead of a wiping motion</p> | A 749 | | | |

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| A 749 | <p>Continued From page 154</p> <p>High Level Disinfecting of Non- TEE Transducers:</p> <p>1.) Clean the transducer and cable according to the procedures in "Cleaning Non-TEE Transducers, cables, and connectors."</p> <p>2.) After cleaning, choose a high-level disinfectant that is compatible with your transducer Follow the label instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. If a pre-mixed solution is used, be sure to observe the solution expiration date.</p> <p>3.) Using an appropriate disinfectant for the cable and connector, wipe or spray the cable, strain relief, and connector, following disinfectant label instructions for temperature, wipe durations, solution strengths, and duration of disinfectant contact</p> <p>4.) Immerse the transducer into the appropriate disinfectant for your transducer as shown in the figure (figure on page 48) following this procedure.</p> <p>5.) Follow the instructions on the disinfectant label for the duration of transducer immersion. Do not immerse transducers longer than the minimum time needed for your level of disinfection.</p> <p>Sterilizing Non- TEE Transducers:</p> <p>-Sterilization is required if the transducer enters</p> | | | A 749 | | | |

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| A 749 | <p>Continued From page 155</p> <p>otherwise sterile tissue without a cover. If you use a sterile cover, sterilization is still recommended, but high- level disinfection is acceptable. The main difference between sterilization and high level disinfection is the length of time that the transducer is immersed and the type of disinfectant or sterilant that is used.</p> <p>In an interview conducted on 4/01/19 at 1:30pm, Infection Control Preventionist#14, verified that ultrasound staff were using the Sani-Cloth HB Quaternary Ammonium (QUAT) wipes to clean the transvaginal transducer prior to placement into the Trophon (high level disinfection system for ultrasound probe processing.</p> <p>Review of the employee training records for Staff#122 revealed no evidence (prior to 3/28/19) of infection control training or training in the proper disinfection of vaginal transducers.</p> <p>C.) Pharmacy: During observations conducted with the onsite pharmacist (Staff #120), a sterile compounding room was observed in the pharmacy area. Upon inspection, the positive pressure room sensor was alerting for a pressure breach. When the external ante room door was opened, it was observed that the interior door to the sterile area had been left open. A large floor dust mop was observed in the corner of the ante room. Upon noticing the open internal door, the pharmacist (#120) picked up the floor dust mop, crossing the sterile barrier, and pushed the interior door closed using the bottom (floor cleaning portion) of the dust mop.</p> <p>In an interview conducted on 3/27/19, at the time of observation, the onsite pharmacist stated that</p> | A 749 | | | |

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| A 749 | <p>Continued From page 156</p> <p>the reason she used the floor dust mop to close the interior compounding room door, was because: "I thought it was better to use that (dust mop) than to contaminate the area with the bottom of my shoes."</p> <p>D.) On 03/26/2019 at 2:30 PM, an inspection was conducted of the hospital Ultrasound room. It was observed that room #4 had a sign that read "Room is clean and available". When asked what the sign meant, the Ultrasound manager #197 replied, "the room has been cleaned and is available for the next patient procedure". A large biohazard box was observed inside the room. Inside the box was a red biohazard plastic bag that contained two large plastic containers with brown liquid inside each of them. Ultrasound employee #198 indicated that the previous patient had a Paracentesis procedure. The employee also stated that the room gets cleaned by housekeeping, however the biohazard staff only comes once a day to collect all biohazards.</p> <p>"Paracentesis is a procedure in which a needle or catheter is inserted into the peritoneal cavity to obtain ascitic fluid for diagnostic or therapeutic purposes. Ascitic fluid may be used to help determine the etiology of ascites, as well as to evaluate for infection or presence of cancer. With regard to differentiation of transudate from exudate, the preferred means for characterizing ascites is the serum-ascitic albumin gradient (SAAG)." Author: Gil Z Shlamovitz, MD, FACEP</p> <p>On 03/26/2019 at 2:32 PM, the biohazard employee was observed collecting biohazard boxes and bags in the ultrasound rooms.</p> <p>On 03/26/2019 at 2:40 PM an interview was</p> | A 749 | | | |

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| A 749 | <p>Continued From page 157</p> <p>conducted with manager #197. During the interview, the manager indicated that the room is considered clean and available even if there is biohazard material waiting to be picked up. When asked if she consider room #4 clean and available, the manager replied "Yes".</p> <p>Record review of Patient #252 was conducted on 03/27/2019. The patient procedure record indicated that Patient #252 had a diagnosis of Cirrhosis of the liver with ascites. A Paracentesis was performed on the patient on 03/26/2019 at 11:24 AM. The procedure ended at 12:02 PM. Patient #252 was checked out of room #4 at 1:28 PM.</p> <p>On 03/28/2019 at 8:45 AM, an interview was conducted with the Hospital Infection Control Committee. This observation was presented to the committee. MD #54 (Infection Control Chief) stated, "Procedure rooms are not consider clean and available until everything that is contaminated from a case is out of the room".</p> <p>E.) On 03/27/2019 at 2:30 PM Environmental Service (EVS)/Housekeeping #124 was observed cleaning a Contact Isolation room.</p> <p>EVS #124 was observed as she was getting ready to clean room # 8A Cooley/room 01. Patient #76 was admitted to the hospital on 01/04/2019 and was on Contact Isolation due to Species (Sputum Culture: + Gram Stain, 1+Pseudomonas Aeruginosa, and 1+Achromobacter). The Contact Isolation order was written on 02/18/2019.</p> <p>EVS #124 was observed washing her hands</p> | A 749 | | | |

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| A 749 | <p>Continued From page 158</p> <p>before beginning the process of cleaning the room. She put on the isolation gown, mask and gloves. She opened her cleaning housekeeping cart drawer and took two washcloths out of the drawer. She entered the patient's room and began cleaning the patient tray table, bed side rails, night stand, door knobs, and bathroom. While wearing her contaminated gloves, she went to her cleaning cart and opened the housekeeping drawer, placing the washcloths inside the biohazard bag. She closed the housekeeping cart drawer while wearing the same contaminated gloves. She left the patient's room and removed her gown, mask and gloves. She was then observed sanitizing her hands with gel.</p> <p>EVS #124 stated that she did not want to contaminate anything. After she applied the sanitizer gel to her hands, she began to prepare her equipment to sweep the patient's room. She put on a gown, mask, and gloves then entered the room. When she was done sweeping, she went back to her cleaning cart and removed the contaminated cloth off from the sweeping pole. She opened the drawer of the cart and placed the sweeping cloth inside the biohazard bag. She did not de-contaminate the sweeping pole.</p> <p>Wearing the same contaminated gloves, EVS #124 took the mop off the cleaning housekeeping cart and began mopping the resident's room. When she finished mopping the floor, she went back to her cart, removed the mop from the pole, opened the drawer of the cleaning cart and placed the mop in the biohazard bag. She placed the mop pole back in the housekeeping cart. She did not de-contaminate the pole.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 159</p> <p>On 03/27/2019 at 2:45 PM, an interview was conducted with EVS #124. During the interview, the she stated that it is important to her to perform her job well. She indicated that EVS/Housekeeping conducts training on how to clean isolation rooms every year.</p> <p>On 03/28/2019 at 8:45 AM, this finding was discussed with the Infection Control Committee. The Infection Control Lead Coordinator #18 stated that she is not sure how the process of cleaning a contact isolation room can be done without contaminating the equipment or supplies.</p> <p>During the same meeting with the Infection Control Committee, MD #54 stated, "We will find a process that maintains the cleanliness of the isolation rooms without re-contaminating equipment."</p> <p>On 03/28/2019 at 3:00 PM, the Director of Environmental Services was interviewed concerning the observation of the cleaning of the isolation room. During the interview he stated that training is conducted every year on different techniques to utilize while cleaning isolation rooms. The Director indicated that floor EVS supervisors should be observing how the EVS employees are performing these tasks.</p> <p>Review of the Standard and Transmission-Based Precautions-Infection Control Policy, effective date: October 2018 and to next review date: October 2021. Page 6/24 (d)(i) Contact Precautions: Designed to prevent transmission between people and between people and objects. This type of transmission occurs when personnel turn or bathe patients or perform other patient-care activities that involve direct contact.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 160</p> <p>Organisms may also be transmitted by personnel, patients or visitors touching or being touched by contaminated objects such as blood pressure cuffs, linens, walkers, stethoscopes, bronchoscopes, and other items.</p> <p>F.) Review of Center for Disease Control Morbidity and Mortality Weekly Report recommend the following practice:</p> <p>Hemodialysis in Acute-Care Settings. For patients with acute renal failure who receive hemodialysis in acute-care settings, Standard Precautions as applied in all healthcare settings are sufficient to prevent transmission of bloodborne viruses. However, when chronic hemodialysis patients receive maintenance hemodialysis while hospitalized, infection control precautions specifically designed for chronic hemodialysis units (see Recommended Practices at a Glance) should be applied to these patients. If both acute and chronic renal failure patients receive hemodialysis in the same unit, these infection control precautions should be applied to all patients.</p> <p>Review of the facility's current infection control plan, revised February 4th 2019 directs staff as follows: "Section 5.03 Infection Control - Developing of Goals and Objectives for 2019: Use of appropriate hand Hygiene by staff, use of appropriate PPE by staff "</p> <p>Registered Nurse 174</p> <p>On 04/01/2019 at 8:45 am, RN #174 was observed on the hemodialysis unit in room #5, at the bedside of Patient (#139). Observation revealed the RN was observed adding powdered</p> | A 749 | | | |

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| A 749 | <p>Continued From page 161</p> <p>potassium to the patient's dialysate concentrate which was attached to the hemodialysis machine.</p> <p>Observation revealed the RN added the powdered concentrate additive to the jug with dialysate solution which contained acid concentrate. RN #174 was not wearing personal protective devices of gloves, gown, and mask. The RN touched the contaminated jug and hemodialysis machine with his ungloved hands. This action puts him at risk for cross contamination and also potential contact with the acid concentrate which could cause actual harm.</p> <p>On 04/01/2019 at 8:48 a.m., RN #174 was observed resetting the panel of the hemodialysis machine of Patient #139. The Patient was receiving hemodialysis treatment and was tethered to the hemodialysis machine. Observation revealed the RN was not wearing a pair of gloves, while in direct contact with contaminated hemodialysis machine.</p> <p>On 04/01/2019 at 9:00 a.m. revealed RN #174 was observed resetting the hemodialysis machine of Patient (#140). The Patient was receiving hemodialysis treatment and was tethered to the hemodialysis machine. Observation revealed the RN was not wearing a pair of gloves, while in direct contact with contaminated hemodialysis machine.</p> <p>Interview on 04/01/2019 at 9:05 a.m. with RN #174. The Surveyor informed RN #174 that he was touching the contaminated hemodialysis machine without wearing gloves. RN #174 stated "I thought because we clean it really good we do not wear gloves."</p> | A 749 | | | |

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| A 749 | <p>Continued From page 162</p> <p>Patient Care Associate #8</p> <p>On 04/01/2019 at 12:03 p.m. Patient Care Associate #8 was observed on the hemodialysis unit of the facility in room #1.</p> <p>The Patient Care Associate was observed terminally cleaning the contaminated bed and side table, post hemodialysis treatment of a patient. Observation revealed the Patient Care Associate was not wearing gown during terminally cleaning of the unit. The Patient Care Associate's clothing was in direct contact with the contaminated bed and hemodialysis machine while terminally cleaning the unit.</p> <p>On 04/01/2019 at 12:20 p.m. during an interview with Patient Care Associate #8, the Surveyor informed her that she was not wearing a gown during terminal cleaning of the unit and that her clothing was in direct contact with the contaminated hemodialysis machine and contaminated bed. Patient Care Associate #8 stated "I am sorry I did not think about it; I should be wearing PPE."</p> <p>Observations on April 1, 2019, on the facility's dialysis unit of the 7th floor revealed the following:</p> <p>Bay 1:</p> <p>8:47am - RN #186 was observed touching the panel of the hemodialysis machine of Patient #166. The Patient was receiving hemodialysis treatment and was tethered to the hemodialysis machine. RN #186 was not wearing a pair of gloves, while touching the contaminated hemodialysis machine.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 163</p> <p>Further observations reveal, RN #186 did not wash/sanitize his hand before touching Patient #166's bedding and then his contaminated hemodialysis machine.</p> <p>9:30 am - The RN #186 arranged P#166 blanket while not wearing gloves. RN #186 then left the patient's room without washing/sanitizing hands, went to type on the computer at the nurses station out of the patient's room. Brought paper work from the common nurse's station to the patient's room. Did not wash hands nor sanitized hands before entering the patient's room. Started to do patient care, touching P#166 contaminated hemodialysis machine and the blood lines to the dialysis machine. Then sanitized hands.</p> <p>Further observation revealed the same RN#186 left the patient room again, did not wash hands nor sanitized hands, to go to the clean utility room. Typed on the key pad, to enter room. Went back to the patient's room. Did not wash/sanitize hands before entering the patient's room and touching the contaminated hemodialysis machine blood lines.</p> <p>Bay 4:</p> <p>9:10am - RN #187 was moving a plastic bin and a temperature gauge in P #164's room. Then RN #187 touched the panel of the contaminate hemodialysis machine. RN #187 was not wearing glove nor did she wash/sanitize her hands.</p> <p>9:23am - RN #187 donned gloves to provide patient care to P#165. RN #187 change the patient sheets and gown. Same RN, with the</p> | A 749 | | | |

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| A 749 | <p>Continued From page 164</p> <p>same gloves, then walked to the other patient. P#164 to fix their blankets and move the blood lines without changing gloves, washing hands nor using hand sanitizer.</p> <p>9:35am - RN #187 arranged the bedding for P#165. RN not wearing gloves. RN #187 went to P#165's bedside computer. Arranged the hemodialysis blood lines, then went back to the bedside computer. RN #187 did not wash/sanitize hands. RN #187 then went to P #164 to arrange his bedding and hemodialysis bloodlines. Did not wash/sanitize hands before or after the patient contact, nor wore gloves.</p> <p>10:00am - RN #187 used a stethoscope on P#164. RN #187 then used the same stethoscope on P#165. Stethoscope was never wiped down before, during, or after use between patients.</p> <p>10:20am - RN #187 was at P #164's bedside, arranging the bedding. RN used the patient scanner on P #164, used the bedside computer, picked up the patient scanner to put away. RN #187 was not wearing gloves, and did not wash/sanitize hands before nor after using the patient scanner or bedside computer.</p> <p>Record review of the facility's current infection control plan, revised February 4th 2019 states in part ... "Section 5.03 Infection Control - Developing of Goals and Objectives for 2019: Use of appropriate hand Hygiene by staff".</p> <p>Record review of the facility's policy, titled Disinfection of Hemodialysis Equipment and Immediate Environment-Dialysis, effective, March 2019, states in part ... "All dialysis machines,</p> | A 749 | | | |

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| A 749 | <p>Continued From page 165</p> <p>ancillary equipment, and other items will be disinfected after each use".</p> <p>J.) Hepatitis B:</p> <p>A review of Staff #77's health record revealed Hepatitis B titer was drawn 01/26/2019 and the result was non-reactive. The facility failed to offer the Hepatitis B vaccine series. Also, there was no documentation as to why the vaccine was not given or follow-up to the Staff #77 non-reactive results.</p> <p>A review of Staff #78's health record revealed Hepatitis B titer was drawn 12/16/2017 and the result was non-reactive. The 1st vaccine of the series was administered 12/18/2017, second dose was 01/15/2018, but Staff #79 never received the third dose vaccine. Further review of the health record revealed there had been no documentation follow-up to Staff #78 since 01/15/2018.</p> <p>A review of Staff #194's health record revealed Hepatitis B titer was drawn 02/23/2019 and the result was non-reactive. The facility failed to offer the Hepatitis B vaccine series. Also, there was no documentation as to why the vaccine was not given or follow-up to the Staff #194 non-reactive results.</p> <p>An interview with RN #206 on 04/04/19, at 9:00 AM, confirmed the facility follows the CDC guidelines for Hepatitis B.</p> <p>A review of the CDC guideline for Hepatitis B vaccine revealed the following:</p> <p>"Hepatitis B vaccine is recommended for</p> | A 749 | | | |

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| A 749 | Continued From page 166 unvaccinated adults who are at risk for hepatitis B virus infection, including: People whose sex partners have hepatitis B Sexually active persons who are not in a long-term monogamous relationship Persons seeking evaluation or treatment for a sexually transmitted disease Men who have sexual contact with other men People who share needles, syringes, or other drug-injection equipment People who have household contact with someone infected with the hepatitis B virus Health care and public safety workers at risk for exposure to blood or body fluids Residents and staff of facilities for developmentally disabled persons Persons in correctional facilities Victims of sexual assault or abuse Travelers to regions with increased rates of hepatitis B People with chronic liver disease, kidney disease, HIV infection, or diabetes Anyone who wants to be protected from hepatitis B Hepatitis B vaccine is made from parts of the | A 749 | | | |

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| A 749 | <p>Continued From page 167</p> <p>hepatitis B virus. It cannot cause hepatitis B infection. The vaccine is usually given as 2, 3, or 4 shots over 1 to 6 months.</p> <p>Not at risk but want protection from hepatitis B (identification of risk factor not required): 2- or 3-dose series Hp B (2-dose series Heplisav-B at least 4 weeks apart [2-dose series HepB only applies when 2 doses of Heplisav-B are used at least 4 weeks apart] or 3-dose series Engerix-B or Recombivax HB at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2, 8 weeks between doses 2 and 3, 16 weeks between doses 1 and 3]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2, 5 months between doses 2 and 3])."</p> <p>A review of the facility policy titled, "Employee Exposure to Hepatitis A, B, C, and HIV (System) effective September 2017 revealed the following:</p> <p>"Because of the high risk of HBV infection among personnel, routine pre-exposure vaccination against hepatitis B is recommended. Studies show the vaccine to be effective in the prevention of infection in 90% or more of recipients.</p> <p>HBIG should be administered intramuscularly as soon as possible after exposure when indicated, The effectiveness of BRiG when administered >7 days after percutaneous, mucosal, or nonintact skin exposures is unknown. HBIG dosage is 0.06 ml/kg.</p> <p>Should be performed 1-2 months after the last dose of the HepB vaccine series (and 4-6 months after administration of HBIG to avoid detection of</p> | A 749 | | | |

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| A 749 | <p>Continued From page 168</p> <p>passively administered anti-HBs) using a quantitative method that allows detection of the protective concentration of antiHBs (>10mIU/mL).</p> <p>A responder is defined as a person with anti-HBs >10 mIU/mL after >3 doses of HepB vaccine.</p> <p>A nonresponder is defined as a person with anti-HBs <10 mIU/mL after >6 doses of HepB vaccine." Etc.</p> <p>An interview with RN #206 on 04/04/2019, at 9:00 AM, confirmed that Staff #77, #78, and #194 had not had follow-up to their hepatitis b titer. Also, that the CDC guidelines for hepatitis b and facility policy had not been followed.</p> <p>K.) Tuberculosis:</p> <p>A review of Staff #78's health record revealed the IGRA for tuberculosis was drawn 11/07/2018 and the result was indeterminate. Also, there was no documentation or follow-up on checking the status of Staff #77's tuberculosis risk.</p> <p>A review of the facility policy titled, "Employee Tuberculosis Screening (System) effective February 2019 revealed the following:</p> <p>"Policy:</p> <p>2. Current Employees</p> <p>a. Current employees with a history of negative TB results are required to have an IGRA test as noted in chart below,</p> | A 749 | | | |

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| A 749 | <p>Continued From page 169</p> <p>b. Current employees with a history of a positive TB result will only need to complete the TB Program Symptom Survey in ReadySet. See Positive IGRA Results.</p> <p>c. Every employee is required annually to complete the TB Program Symptom Survey and Exposure Questionnaire/Survey in ReadySet.</p> <p>d. OHD will send an email notification to employees when the TB Symptom needs to be completed.</p> <p>e. Employee may also provide written proof of TB screening done elsewhere.</p> <p>3. Positive IGRA Results</p> <p>a. If an IGPA result is positive, then OHD will notify employee by phone of the positive result and email employee a CXR order to have performed with the imaging department at their facility.</p> <p>b. A Physician Clearance form will also be emailed to have employee take to their Primary Care Physician for review of the CXR result and evaluation of the employee. Physician must fill out the form to indicate employee is cleared to return to work.</p> <p>c. Employee then drops off, emails or faxes Physician Clearance form to OHD for return to work clearance."</p> <p>An interview with RN #206 on 04/04/2019, at 9:00 AM, confirmed that Staff #78 had not had a</p> | A 749 | | | |

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| A 749 | <p>Continued From page 170</p> <p>follow-up for Tuberculosis. There was no documentation that the facility had monitored or retested after the indeterminate of the IGRA. Also, that the facility policy had not been followed.</p> <p>L.) Fannin and Main Endoscopy Area:</p> <p>While observing the scope high level disinfection process at the Fannin scope processing room on 03/26/2019, Staff #78 was observed to remove the scope from the Automatic Endoscope Reprocessor (AER) and dry the outside of the scope, but failed to air blow the inside of the scope.</p> <p>Follow the facility's policy for processing the endoscopes at the Fannin Facility and in the Main endoscopy area.</p> <p>While observing the scope high level disinfection process at Main endoscopy area in the scope processing room on 03/27/2019, Staff #77 was observed to remove the scope from the Automatic Endoscope Reprocessor (AER) and dry the outside of the scope, but failed to air blow the inside of the scope.</p> <p>A review of the facility policy titled, "Cleaning of Endoscopic Equipment - Endoscopy" revealed the following:</p> <p>"13. After completion of all phases of the AER cycle, use compressed air to blow the scope channels and control knobs dry. The scope should be ready to use. (Note: at least 70% alcohol is recommended in the AER)." Etc.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 171</p> <p>An interview with Staff #77 on 03/26/2019, at 2:00 PM, confirmed she had forgot to air blow out the scope after removing it from the AER.</p> <p>An interview with Staff #78 on 03/27/2019, at 10:00 AM, confirmed she had forgot to air blow out the scope after removing it from the AER.</p> <p>Rapicide Strips:</p> <p>While touring and observing the reprocessing of scopes on 03/26/2019 at Fannin and 03/27/2019 at the Main Endoscopy area, it was observed that Rapicide PA strips were being used for checking the concentration of peracetic acid. The date of expiration written by the Staff on the bottle of Rapicide PA strips was July 18 2019. The expiration on the bottle was June 2019. The staff members were concentrating on the label that says the strips will expire in 4 months and not adhering to the manufacture expiration date. The beyond use date was less than the 4 months.</p> <p>A review of the manufacture instructions for use revealed the following:</p> <p>Important Precautions:</p> <p>"Keep the strips in the original container. Remove only the required strip before testing and immediately replace the cap tightly, Exposure of the uncovered strip to light and moisture may cause discoloration of the strip. Do not use the strip after the expiration date (opened or unopened). Test strips are good for 4 months once opened. Do not touch the reagent pad with finger or any other surface."</p> | A 749 | | | |

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| A 749 | <p>Continued From page 172</p> <p>An interview with Staff #77 on 03/26/2019, at 2:00 PM, confirmed the Rapicide PA strips were dated beyond the use date.</p> <p>An interview with Staff #78 on 03/27/2019, at 10:00 AM, confirmed the Rapicide PA strips were dated beyond the use date.</p> <p>Jun-Air Quiet Compressor:</p> <p>While touring and observing the reprocessing of scopes on 03/26/2019 at Fannin and 03/27/2019 at the Main Endoscopy area, observed that the JUN-AIR Compressor filters were covered with thick white lint. There were 2 JUN-AIR compressors in each of the reprocessing rooms. The JUN -AIR compressors are used to filter the air from the peracetic acid used in the high level disinfection Automatic Endoscope Reprocessor (AER). Surveyor questioned when had the filters been changed or cleaned. Staff #77 stated, "I don't know."</p> <p>A review of the JUN-AIR compressor preventive Maintenance instructions revealed the following:</p> <p>"The external filters can be changed without opening up the compressor. Remove the filter located in the front of the compressor and discard, replace with a new foam inlet filter."</p> <p>M. During a tour on March 25, 2019 after 2:00 PM, the following observations were made:</p> <p>MAIN OR</p> <p>SECTION A STERILE CORE</p> | A 749 | | | |

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| A 749 | <p>Continued From page 173</p> <p>The Refrigerator in A Sterile Core had a seal at the top of the refrigerator door that was covered in a black substance appearing to be mildew. There was an open bottle of RPMI medium (a pathology fixative) stored in the same refrigerator as Sodium Chloride intravenous fluid.</p> <p>ORTHOPEDIC CORE</p> <p>There was an Integra Bovine Pericardium tissue graft stored inside a closed cabinet. Temperature storage limits on the package were listed as 15 degrees Celsius to 30 Celsius. Temperature requirements as recommended per manufacture recommendations were not being monitored. RN #212 confirmed they were not monitoring temperature inside of the cabinet. RN # 212 also confirmed they were not aware that the tissue had temperature requirements for storage.</p> <p>UROLOGY-CYSTO ROOM 3</p> <p>The kick bucket basin was coated in rust. An IV (Intravenous) pole had chips of paint missing on the base of the pole. There was a stool in the room that had a tear in the vinyl covering. There was rust in the basin of the fluid irrigation warmer. The Velcro that attached the OR mattress to the OR table was stained in brownish color residue. The OR mattress had tears in the vinyl covering.</p> <p>UROLOGY CORE</p> <p>An equipment cart that had an Olympus Shock Pulse-SE (a lithotripsy machine used for efficient stone fragmentation in urology cases) had chips of missing paint and rust.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 174</p> <p>During a tour on March 29, 2019, after 10:00 AM, the following observations were made:</p> <p>MAIN OR</p> <p>OPERATING ROOM 21</p> <p>There was suction tubing hanging on the suction canister hanging on the wall outside of manufacturer package and uncovered. There was no way to determine if the suction tubing was clean. The tubing was in a room that had been cleaned and was ready for patient use. There was an irrigation fluid warmer that had rust in the basin. There was a stool that had a tear in the vinyl covering. There was rust and missing chips of paint on the stool base. There was a metal table that had rust on the wheel casters. There was an IV pole with chips of paint missing on the base. The IV pole had rust on the wheel casters. The anesthesia supply cart had 4x4 sponges stored in a bin inside a drawer of the cart. The sponges were stored in an open fashion uncovered. The sponges were exposed to build up of dust, dirt, and contamination. There was a radial artery catheterization set stored in the anesthesia supply cart that expired 09-2018; over 6 months prior. The catheterization set was stored in a cart with supplies that were available for patient use.</p> <p>OPERATING ROOM 18</p> <p>There was an IV pole that had chips of paint missing on the base. There was a robotic surgery equipment tower that had rust in the bin that stored the oxygen/gas tanks. The operating room door had chunks of wood missing from the base</p> | A 749 | | | |

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| A 749 | <p>Continued From page 175</p> <p>of the door on the inside of the operating room. The plasterboard/wood was exposed. The operating room door had cracks and chips of paint missing on the door and the door frame.</p> <p>HALLWAY OUTSIDE OR 16</p> <p>Next to the scrub sink at the base of the wall the baseboard had a hole in the wall that connected to the floor. There was plaster/sheetrock that was exposed.</p> <p>MAIN OR HALLWAY</p> <p>There was a Pentax Endoscopy tower stored in a hallway. There was rust on the screw base that attached the base legs to the wheel caster.</p> <p>RN #6 & #212 confirmed the above findings.</p> <p>During a tour on March 27, 2019 after 9:00 AM the following observations were made:</p> <p>MAIN OR</p> <p>STERILE PROCESSING DEPARTMENT (SPD)</p> <p>There were cracks in the linoleum flooring. A metal cabinet that stored green towels used to decontaminate operating room instruments was coated on the inside of the cabinet in a white substance and had a build- up of dust, dirt, and debris. A metal drawer in the cabinet was coated in dust, dirt, and debris. On the back wall behind the sink stations and next to the automatic washers, the base of the wall that connected to the linoleum had chips of paint missing. The seal in the crevices was cracked and disintegrating. There was a build-up of dust, dirt, and debris in</p> | A 749 | | | |

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| A 749 | <p>Continued From page 176</p> <p>the crevices. The floor under a metal shelf and next to the water valves had a rubber seal that had disintegrated and the subfloor was exposed. There was a build-up of dust, dirt, and debris in the crevices.</p> <p>RN#6 and Staff #'s 2&72 confirmed the findings.</p> <p>FANNIN SURGERY</p> <p>During a tour on March 26, 2019, after 10:00 AM, the following observations were made:</p> <p>OPERATING ROOM 6</p> <p>There were rust and missing chips of paint at the base of operating room table. There were tears and cracks in the linoleum floor. There were cracks and tears in the OR mattress. There was rust on the linen hamper. There were scrapes and missing chips of paint on the OR walls.</p> <p>OPERATING ROOM 11</p> <p>There was a tear/crack in the vinyl covering of the stool. The base of the stool had missing and chipped paint. The walls had scrapped/missing chips of paint. There were cracks and tears in the OR mattress. There was rust and missing chips of paint on the Covidien equipment cart. There were tears and cracks in the linoleum. There was rust and missing chips of paint on the cystoscopy OR table attachment. There was rust and missing chips of paint on the Covidien equipment cart.</p> <p>OPERATING ROOM 12</p> <p>The baseboard next to the door frame outside of</p> | A 749 | | | |

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| A 749 | <p>Continued From page 177</p> <p>the room had a hole in the covering. The hole exposed plaster from the wall.</p> <p>STERILE SUPPLY/EQUIPMENT CORE</p> <p>There was a metal cart used to transport irrigation fluid to the operating rooms for arthroscopic orthopedic cases. The frame was coated in rust.</p> <p>OR HALLWAY</p> <p>There was a metal rack containing sterile supplies. The rack had two boxes of corrugated cardboard boxes that contained Arthrex Orthopedic sterile supplies stored on it. The supply cart was in the surgery restricted area.</p> <p>Review of the AORN (Association of perioperative Registered Nurses) 2019 Perioperative Standards and Recommended Practices, Guidelines for Sterilization, revealed the following:</p> <p>" ...Recommendation IV.c. Supplies and equipment should be removed from external shipping containers and open-edged corrugated cardboard boxes before transfer to the sterile storage area or point of use.</p> <p>External shipping containers and open-edged cardboard boxes may collect dust, debris, and insects during shipment and may carry contaminants into the surgical suite ..."</p> <p>Review of ANSI/AAMI ST79:2017 revealed the following:</p> <p>"11.1 Sterile Storage</p> | A 749 | | | |

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| A 749 | <p>Continued From page 178</p> <p>Sterile items should be stored under environmentally controlled condition that reduces the potential for contamination ...</p> <p>Supplies should be removed from external and web-edged shipping container before transport to any restricted area ..."</p> <p>STERILE SUPPLY CORE</p> <p>A refrigerator in the sterile supply core had RPMI medium and sperm washing medium (a pathology fixative) that was stored in the same refrigerator next to normal saline and water irrigation bottles/normal saline intravenous fluid.</p> <p>RN #6 confirmed the above findings.</p> <p>CATH LAB</p> <p>During a tour on April 1, 2019 after 9:00 AM the following observations were made:</p> <p>STERILE INSTRUMENT STORAGE</p> <p>There was a nasal Speculum stored with pacemaker instruments. The speculum was processed 12-20-2016. McGill forceps stored on the intubation tray was processed in 3-6-2010. Staff interviews revealed the Cath Lab staff was not trained on the peel pack time limits. Cath lab staff said that the peel packs were considered sterile one year after processing.</p> <p>Review of the Instructions for Use (IFU) for Cardinal Health Self seal pouches did not reveal a time limit on peel pack sterility after sterilization.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 179</p> <p>During an interview with Staff #2 on 3-29-2019, Staff #2 said the peel pack pouches were event related. Staff #2 said the Cardinal Peel packs were considered sterile unless the integrity of the pouch was comprised or punctured.</p> <p>CATH LAB EQUIPMENT ROOM</p> <p>The ultrasound machine had a build-up of dust, dirt, and debris in the crevices. There was rust on the metal screws. There were ceiling tiles above the equipment that were bulging and had missing pieces of the tile.</p> <p>The Laser glasses had a white substance on the lenses. RN #178 was asked if the glasses were scratched or dirty. RN #178 said, he was not sure. RN #178 was asked to wipe lenses to determine if the glasses had been put in container for storage dirty. RN #178 used an alcohol wipe to clean lenses. The white substance easily wiped off when cleaned.</p> <p>6 TOWER ROOM 634</p> <p>There was a buildup of dust, dirt, debris in the corners of the floor in the bathroom.</p> <p>There was a buildup of dust, dirt, and debris on the tile base in the bathroom.</p> <p>During a patient tracer on April 1, 2019, after 9:00 AM, the following observations were made:</p> <p>6 TOWER (SURGERY PRE-OP AREA)</p> <p>RN #179 was observed going into Patient #146's Pre-Op room on 6 Tower. RN #179 carried a</p> | A 749 | | | |

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| A 749 | <p>Continued From page 180</p> <p>WOW (Workstation on wheels) into the room. The WOW was not cleaned prior to going into the room. When RN #179 used the stethoscope to assess the patient's lung and heart sounds, the stethoscope was not completely wiped down prior to using on the patient. RN #179 wiped down the earpieces and the bell. RN #179 did not wipe down the tubing that connects the two. After completing the assessment, RN #179 wiped down the earpieces and the bell again and hung the stethoscope around her neck. RN #179 did not wipe down the tubing that connects the two after using on the patient. After completion of the Pre-Op assessment, RN #179 pushed the WOW outside of the room. RN #179 did not clean/wipe down the WOW. RN #179 was asked how often the WOW was cleaned. RN #179 said that it was cleaned once a week usually. RN #179 was asked if the WOW was cleaned after it was taken into a patient's room. RN #179 confirmed it was not cleaned unless it had visible contaminates on it.</p> <p>CATH LAB #10</p> <p>There was no separation between semi restricted and restricted areas in the Cath lab surgical procedure room. The Cath lab procedure room is used to perform sterile procedures, failed to have any type of division between the surgical area and the non surgical areas. Surgical scrub staff are wearing sterile gowns and gloves and there is a sterile instrument table yet there is no control over or protection of these areas from the potential of contamination.</p> <p>The C-Arm base was covered in rust, dirt, debris. The C-Arm base had chips of paint missing. The Cath lab table had rust and dirt along the base.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 181</p> <p>The linen hamper had rust on the frame and the lid. The entrance to the equipment room had rust at the base of the door frame. The wall next to the door frame had holes in the wall that exposed plaster. The door frame going to the main hallway had chips of paint missing. The air vent was covered in dust, dirt, and debris. There was a metal table that had a missing protective cap on the pole. The edge was sharp and posed a risk of staff injury. The poles on the table were covered in rust.</p> <p>Staff #182 was observed to be functioning in the role of Cath lab scrub for Patient #146's Cath procedure. Staff #182 was observed going in and out of the Cath lab room several times prior to setting up and opening the sterile field for the case. Staff #182 was wearing a mask each time he left the room. When Staff #182 returned to the room the mask was still on. Staff #182 did not change the mask upon re-entering the room. Staff #182 began opening the sterile supplies with the same mask he was wearing when he went in and out of the room. After opening supplies on the sterile field, Staff #182 turned toward the bed (away from the sterile field) and layed a gown on the Cath lab table. Staff #182 opened the gown up in a sterile fashion and left the gown laying on a sterile drape on the bed. RN #178 was asked why the sterile gown was not opened on the sterile field. RN#178 said he did not know.</p> <p>While observing Staff #182 prep the incision site, the following was observed:</p> <p>Staff #182 used a Chloraprep applicator to prep the incision site. Staff #182 was observed to start the prep in the groin area, then prep down the leg distally. Using the same prep, Staff #182 prepped</p> | A 749 | | | |

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| A 749 | <p>Continued From page 182 back up the leg to the incision site.</p> <p>Review of the IFU (Instructions for Use) provided by the facility revealed the following:</p> <p>"Apply Once the solution is visible on the skin, completely wet the treatment/incision area with antiseptic, using gentle back and forth strokes for 30 seconds or two minutes, progressing from the incision site to the periphery of the surgical field."</p> <p>Review of the facility policy titled, "Prep: Routine Skin Scrub" with an effective date of February 2019 revealed the following:</p> <p>"PROCEDURES</p> <p>1.Manufacturer's recommendations for skin prep will be followed ..."</p> <p>RN # 178 confirmed the above findings.</p> <p>CVOR (Cardio Vascular Operating Room)</p> <p>On April 2, 2019 after 8:30 AM during a tour the following observations were made:</p> <p>In the CVOR storage area there were Coyote over the wire catheters (3) that expired 3-31-2019; 2 days prior. The catheters were on a cart of supplies that were available for patient use.</p> <p>There were corrugated boxes that contained sterile supplies (Medtronic BIO-MEDICUS Guidewires.) The corrugated boxes were stored on a shelf with other sterile supplies in the CVOR storage area. This storage area was in the</p> | A 749 | | | |

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| A 749 | <p>Continued From page 183 surgery restricted area.</p> <p>RN #6 confirmed the above findings.</p> <p>6 TOWER COOLEY BUILDING</p> <p>ROOM 627</p> <p>There was a buildup of dust, dirt, and debris in the corners of the floor of the room and bathrooms. There were tears in linoleum flooring. The floor seals were disintegrated and left gaps in the floor where the linoleum joined together. There was a buildup of dust and dirt in the crevices where the linoleum joined. The metal trash can was rusted along the base.</p> <p>ROOM 628</p> <p>There was a buildup of dust, dirt, and debris in the corners of the floor of the room and bathrooms. There were tears in linoleum flooring. The floor seals were disintegrated and left gaps in the floor where the linoleum joined together. There was a buildup of dust and dirt in the crevices where the linoleum joined. The metal trash can was rusted along the base.</p> <p>RN #6 confirmed the above findings.</p> <p>JAMAIL SURGERY CENTER</p> <p>During a tour on March 28, 2019 after 9:00 AM the following observations were made:</p> <p>Floors throughout the surgery area had floor seals that were disintegrated and left gaps where</p> | A 749 | | | |

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| A 749 | <p>Continued From page 184</p> <p>the linoleum joined together. There was a buildup of dust, dirt, and debris in the gaps.</p> <p>OR 1</p> <p>A bottle of ISPAN (an intraocular gas) was stored in a cabinet of the operating room. The bottle had a luer lock on the end of the adapter. The luer lock was open and uncapped. The bottle was being used to transfer gases to the sterile field. The luer lock was not changed between patients and was not capped after use. The end of the luer lock was open and exposed to contamination. Surgical 4x4 sponges were stored in a bin open and uncovered exposing them to decontamination, and dust buildup.</p> <p>ENVIRONMENTAL SERVICES CLOSET</p> <p>Upon opening the closet door, observed gnats flying in the air. There were gnats on the wall and coming up out of the drain. There was a buildup of dust, dirt, and debris on the floor. There was trash in the broom trash holder. There was a mop base stored on top of the towels used to clean the OR's. The mop base had a buildup of dust, dirt, and lint. The sink in the closet was covered in dust, dirt, and rust.</p> <p>There was a cart used to store supplies for terminally cleaning the operating rooms. The cart had a buildup of dust, dirt, and debris. There was a dead roach in a crevice on the cart. There was a Rubbermaid bin stored on the cart. The Rubbermaid bin had water in it. The water had a sour smell, dirt and dead bugs in it.</p> <p>LINEN CART</p> | A 749 | | | |

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| A 749 | <p>Continued From page 185</p> <p>There was a linen cart in the hallway of the pre-operative area that was covered in rust at the base and on the metal racks.</p> <p>RN #6 confirmed the above findings.</p> <p>STERILE PROCESSING DEPARTMENT (SPD)-JAMAIL</p> <p>There were Microstar sterile injectors X 4- used for delivery of cataract IOL lenses stored on a rack in the Sterile Processing department. The Injectors expired 2-2019, over 2 months ago.</p> <p>During observation in the decontamination room Staff #75 was asked to explain the process for the Steris automated washer. Staff #75 said, the facility didn't use the washer that much but explained the process to use it. Staff #75 was asked to provide the Washer test log books. Staff #75 said, they did not test the washer since they did not use it much.</p> <p>Staff # 199 confirmed the above findings.</p> <p>Review of the document titled, "Verify All Clean Washer Indicator Test" for monitoring cleaning processes provided by the facility revealed the following:</p> <p>"1. Make sure the holder is clean and dry. Insert indicator strip into holder.</p> <p>2. Place holder with one soil stain facing down and the other facing vertically, as shown above.</p> <p>3. Place empty basket with holder into a rack.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 186</p> <p>4. Interpret - Carefully remove the All Clean Test Indicator Strip from the holder. Inspect by placing plastic against a white background. Compare the results against the samples below to determine a pass or fail. If the color remains visible, the result is FAIL."</p> <p>Review of the document "VERIFY All Clean Test Washer Indicator" provided by the facility revealed the following:</p> <p>"Title:</p> <p>Monitoring and verifying automated instrument washer/disinfector cycles with the use of the Verify All Clean Test Wash Indicator.</p> <p>Purpose:</p> <p>The first step in processing a medical device is decontamination. To ensure that mechanical cleaning equipment is working properly, and according to manufacturer's specifications, health care personnel may perform verification tests as part of the overall quality assurance program. Methods of verification include the use of devices that directly test individual instruments for residual soils, challenge cleaning effectiveness with standardized test methods, or measure specific key parameters to evaluate the functionality of the cleaning equipment. (ANSI/AAMI ST79:2009, 10.2)</p> <p>Procedures:</p> <p>NOTE: The washer/disinfector loads will be monitored with the Verify ALL Clean Test Washer</p> | | | A 749 | | | |

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| A 749 | <p>Continued From page 187</p> <p>Indicator</p> <p>Initiating the Cycle:</p> <p>....3. Place one All Clean Test Indicator into the holder ensuring it is centrally placed and not protruding from either side.</p> <p>4. At the beginning of each day, the device should be run in a complete EMPTY load to establish a control.</p> <p>Staff #199 confirmed the above findings.</p> <p>During review of the Sterile Processing load documentation revealed several loads noting dermatology sets that were processed. Staff # 75 said, the department processed instrument sets for the dermatology office upstairs in the building. Staff #75 was asked to explain the process for the sterilization of instruments brought in from outside source. Staff #75 said, the sets were brought down and put in a designated area by the dermatology office staff. Staff #75 said, the SPD staff would pick the instrument sets up, wrap them, sterilize them, and return to the designated area. Staff #75 was asked how the instruments were washed/decontaminated. Staff #75 said, the office staff washed them before they brought them down. Staff #75 was asked how the SPD department would ensure the instruments had been properly decontaminated. Staff #75 said, there was no way to ensure that with the process currently in place.</p> <p>Review of the sterilization load logs from 2-1-2019 to 3-27-2019 revealed that 120 dermatology instrument sets were processed at the facility during that time. Staff #75 confirmed that none of the sets were decontaminated at the</p> | A 749 | | | |

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| A 749 | <p>Continued From page 188 facility prior to sterilizing the sets.</p> <p>Staff # 2 was asked to provide the contract and policy for processing instruments from outside facility.</p> <p>The following facility policy was provided:</p> <p>"Borrow/Lend Receipt - Central Sterile Processing (SCPD)", March 2017</p> <p>....1. Any instrumentation (item/set) borrowed from any vendor, outside hospital, etc. will be reprocessed in CSPD. Vendors must bring an accurate count sheet before the set will be processed. After the borrowed item/set has been counted and documented, they will proceed through decontamination, assembly, and sterilization"</p> <p>Staff #2 said this was the only policy related to processing instruments from outside departments. Staff #2 also said there was no contract to process the dermatology instruments.</p> <p>TEMPERATURE AND HUMIDITY LOGS</p> <p>The facility failed to ensure the temperature in the Operating room (OR) was within acceptable standards to inhibit microbial growth, reduce the risk of infection, promote patient comfort, and assure the physical safety of all patients. The temperature was out of range for 24 of 24 days reviewed. There was no documentation on the log to indicate corrective action taken and the temperature on follow up after corrective action was done.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 189</p> <p>Review of the Temperature Logs for March 1 to March 27, 2019 revealed the following:</p> <p>MAIN OR</p> <p>AHU-E3-1 OR'S</p> <p>OR #9 - The temperature was documented out of range 24 of 25 days.</p> <p>OR #10 - The temperature was documented out of range 24 of 25 days.</p> <p>OR #11 - The temperature was documented out of range 23 of 25 days.</p> <p>OR #12 - The temperature was documented out of range 17 of 25 days.</p> <p>OR #14 - The temperature was documented out of range 18 of 25 days.</p> <p>OR #15 - The temperature was documented out of range 19 of 25 days.</p> <p>AHU-E3-2 OR'S</p> <p>OR #1 - The temperature was documented out of range 10 of 25 days.</p> <p>OR #2 - The temperature was documented out of range 23 of 25 days.</p> <p>OR #8 - The temperature was documented out of range 22 of 25 days.</p> <p>OR #16 - The temperature was documented out of range 20 of 25 days.</p> | A 749 | | | |

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| A 749 | Continued From page 190 OR #17 - The temperature was documented out of range 24 of 25 days. OR #18 - The temperature was documented out of range 17 of 25 days. AHU-E3-3 OR'S OR #3 - The temperature was documented out of range 19 of 25 days. OR #6 - The temperature was documented out of range 6 of 25 days. OR #7 - The temperature was documented out of range 24 of 25 days. OR #19 - The temperature was documented out of range 24 of 25 days. AHU-E3-4 OR'S OR #4 - The temperature was documented out of range 9 of 25 days. OR #5 - The temperature was documented out of range 24 of 25 days. OR #20 - The temperature was documented out of range 14 of 25 days. OR #21 - The temperature was documented out of range 23 of 25 days. OR #25 - The temperature was documented out of range 20 of 25 days. | A 749 | | | |

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| A 749 | <p>Continued From page 191</p> <p>AHU-E3-5 OR'S</p> <p>OR #22 - The temperature was documented out of range 15 of 25 days.</p> <p>OR #23 - The temperature was documented out of range 24 of 25 days.</p> <p>OR #24 - The temperature was documented out of range 5 of 25 days.</p> <p>There was no temperature log provided for March 6 or the 8th.</p> <p>CATH LAB</p> <p>There was no documentation for temperature or humidity in the Cath lab from November 2018 to present (March 2019). RN #213 and Staff #200 confirmed the Cath lab did not have any documentation of the temperature.</p> <p>FANNIN SURGERY CENTER</p> <p>Temperature and Humidity Logs were provided for one day at the surgery center.</p> <p>Review of the temperature and humidity log for March 28, 2019 revealed the following:</p> <p>OR 1 - The temperature was documented out of range.</p> <p>OR 2 - The temperature was documented out of</p> | A 749 | | | |

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| A 749 | <p>Continued From page 192 range.</p> <p>OR 4 - The temperature was documented out of range.</p> <p>OR 5 - The temperature was documented out of range.</p> <p>OR 6 - The temperature was documented out of range.</p> <p>OR 7 - The temperature was documented out of range.</p> <p>OR 8 - The temperature was documented out of range.</p> <p>OR 10 - The temperature was documented out of range.</p> <p>OR 12 - The temperature was documented out of range.</p> <p>ENDO 1 - The temperature was documented out of range.</p> <p>Review of the AORN Perioperative Standards and Recommended Practices,</p> <p>"Temperature should be maintained between 68 degrees F to 75 degrees Fahrenheit (20 degrees to 23 C) within the operating room suite. General work areas in sterile processing should be maintained between 68 degrees to 73 degrees F.</p> <p>Relative humidity should be maintained between 20% and 60% within the perioperative suite, including operating rooms, recovery area, cardiac</p> | A 749 | | | |

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| A 749 | <p>Continued From page 193</p> <p>catheterization rooms, endoscopy rooms, instrument processing areas, and sterilizing areas and should be maintained below 60% in sterile storage areas.</p> <p>Low humidity increases the risk of electro static charges, which pose a fire hazard in an oxygen-enriched environment or when flammable agents are in use and increases the potential for dust. High humidity increases the risk of microbial growth in areas where sterile supplies are stored or procedures are performed.</p> <p>Humidity should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system.</p> <p>Temperature should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system."</p> <p>Review of the facility policy titled, "Operating Room HVAC Pressure Relationships, Room Temperature, & Humidity Monitoring, Inspection & Testing-Facilities Engineering" with an effective date of February 2019 revealed the following:</p> <p>"Room Temperature & Humidity Monitoring:</p> <p>1.All operating rooms ventilation, temperatures and humidity is reported to the building automation system (BAS) on an hourly basis.</p> <p>Monitoring and Response:</p> <p>.... If BAS adjustments do not bring the room</p> | A 749 | | | |

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| A 749 | <p>Continued From page 194</p> <p>back into specified range within two hours (Appendix A), a facilities technician will be dispatched to assess and correct the condition ..."</p> <p>Appendix A - Ventilation Requirements for Hospitals and Outpatient Facilities</p> <p>Operating/Surgical cystoscopy rooms - Relative Humidity 30-60 %, Design Temperature 68-73 degree Fahrenheit ..."</p> <p>N.) During an observation on 03/26/2019 after 9:20 a.m., the following was observed:</p> <p>Main Emergency Department Triage room</p> <p>An EKG (electrocardiogram) machine was observed to have a piece of paper taped down on the top of the equipment. The tape had turned brown and was soiled.</p> <p>Plastic bins on the cart in which the EKG machine was encased in were soiled with a brown build-up. The gray outside covering of the cart was missing sections. There was no way the cart could be sanitized.</p> <p>A metal supply cart in the room had wheel castors that were covered with rust. The wheels were also soiled with dust and one had remnants of a dressing wrapped around it.</p> <p>Speech and Rehab Manager #87 and Quality Data coordinator #88 confirmed the observations.</p> <p>Kirby Glen Center</p> | A 749 | | | |

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| A 749 | <p>Continued From page 195</p> <p>During an observation on 03/27/2019 after 9:01 a.m., the following was observed:</p> <p>Patient Bay #13 was identified as clean and ready for a patient. Trash was found in the trashcan. The patient recliner had wheel casters that were rusted.</p> <p>Patient Bay #12 was identified as clean and ready for a patient. Trash and used gloves were found in the trashcan.</p> <p>The patient recliner in the room had tears exposing the white cushion inside.</p> <p>The infusion pump was soiled with a dried brown substance on the outside. Spills were on the stand where the pump was. The pole that the pump was on had brown dried spills down it.</p> <p>Room #11 had a bed in it. The frame on the bed had remnants of paper and tape on it that were soiled. The mattress was ripped exposing the cushion.</p> <p>The cartridge was removed from the infusion pump and the inside was soiled with a dried brown substance.</p> <p>Patient Bay #10</p> <p>A patient recliner had wheel castors which were rusted.</p> <p>Clean supply room</p> <p>The tile floor in the room was soiled with spills and stained with dark brown substance underneath the shelves of clean supplies.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 196</p> <p>RN#115 confirmed the observations. RN#115 stated, the nurse clean the rooms after each patient and environmental services cleans every evening.</p> <p>Transfusion Observation</p> <p>During an observation on 03/27/2019, after 10:13 a.m., a cooler container with bags of blood was placed on the floor in Patient #92's bay without any protective barrier underneath it.</p> <p>RN #127 donned clean gloves and opened up the cooler. RN #127 was observed handling the lower part of the cooler when she was trying to open it. A bag of blood was removed from the cooler without changing her gloves first.</p> <p>Main Pharmacy:</p> <p>Four rolling carts were sitting in the middle of the pharmacy. Two of the carts had empty bins stacked on top. The carts were used to take medications to the different floors of the hospital. The carts were soiled with dust and debris. The carts were not cleaned each time they were brought back into the pharmacy. The pharmacy had no designated clean and soiled areas.</p> <p>Crash carts were brought into the main area of the pharmacy to be restocked. The carts had already been to central supply. The side of the carts were soiled red sharps containers. The containers had dirty needles, medication vials, blood tubes, and bloody needles inside.</p> <p>An interview with Staff #9 confirmed there was no specified clean or dirty area of the pharmacy.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 197</p> <p>Staff #9 also confirmed the crash carts had soiled sharps containers inside. Staff #9 stated, "I was not aware the containers had anything in them. The carts are supposed to go to central supply first and be restocked and the sharps containers replaced. Then they are supposed to come to us."</p> <p>Patient Floor 7 South 1 and 2:</p> <p>The medication refrigerator on 7 South was found to be iced over in the back, soiled with dust and debris.</p> <p>The locked wooden medication cabinets were found to have blue bins with medications in the bins. The bins were soiled with dust and debris.</p> <p>A locked wooden medication cabinet was found to be marked "Dialysate 2K/3Ca." The locked cabinet next to it was marked "Dialysate 4K/3Ca." Inside the locked cabinets, plastic bins were found. The bins that held the bags of Dialysate were soiled with dust, hair, and white substance.</p> <p>Outside the locked wooden medication cabinets revealed the floor molding was missing from the wall. The floor/wall area was heavily soiled with a mold substance, dirt, and debris. The tile floor was soiled with dirt and long black hairs.</p> <p>The Pyxis system is an electronic cabinet that holds medications. The outside of the main Pyxis was soiled with dried spills and dust.</p> <p>Inside the Pyxis cabinet, the bottom drawer was found to have Sodium Chloride Irrigation solution sitting in a dirty container. The container was soiled with dust, hair, and debris.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 198</p> <p>Review of the medication refrigerator revealed it was soiled with dust and debris.</p> <p>7 South 4/5 Neuro floor:</p> <p>7 South 4/5 Neuro floor was found to have a medication refrigerator. The refrigerator door was soiled with old tape residue, and the plastic seal to the door was cracked and broken. The back of the wall on the inside was iced over and unable to be cleaned properly.</p> <p>Loading Dock:</p> <p>Dirty sharps containers holding needles, medications, chemotherapy wastage, and bloody products were being stored for pick up in trucks from a contracted company. The truck storage area was heavily soiled on the floor with dried spillage and dirt. The company personnel confirmed clean materials can be placed in the same dirty trucks that picked up contaminated items. Dirty sharps containers holding needles, medications, chemotherapy wastage, and bloody products were being stored for pick up on the outside dock. Some of the containers were empty. The contracted employees confirmed some were dirty for pick up and some clean stored together on the same dock.</p> <p>An interview was conducted with Staff #31 in the morning of 3/28/19. Staff #31 reported that Environmental Services (EVS) occasionally receive calls that sharp containers are full and need to be picked up. EVS will contact ____ (contracted company) to pick up. The contracted</p> | | | A 749 | | | |

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| A 749 | <p>Continued From page 199</p> <p>company goes into the patient's rooms to pick up the containers. Staff #31 was asked what type of education or training had the _____ (contracted company) employees had to enter isolation rooms or contaminated areas? Staff #31 stated, he was not sure. The facility was unable to verify the contracted company employees were trained or oriented in prevention of the spread of infections for the facility and the outpatient areas.</p> <p>Kirby Glen Unit:</p> <p>At the Kirby Glen Unit, a wooden cabinet was found holding a medication refrigerator. The wooden cabinet had a large piece of missing Formica at the bottom. The cabinet had exposed wood and was unable to be cleaned.</p> <p>The patient nourishment refrigerator was found to be soiled with dust and dried spilled liquids.</p> <p>Patient Room 6 was clean and ready for a patient. The mattress on the stretcher was found to be soiled with a dark brown substance.</p> <p>The stretcher was heavily soiled with dirt and dirt type particles. Old tape was placed over the IV pole hole and side rails. The tape was covered in dirt, dust, hair and dried liquid substances.</p> <p>The IV pole was rusted and paint was missing and chipped on the bottom frame.</p> <p>The pharmacy had a wooden Dutch Door. The veneer on the bottom door was missing and chipped in spots. The wood was exposed and unable to be cleaned properly. Gray plastic bins were found just inside the pharmacy on a cart. The bins were ready for medication</p> | A 749 | | | |

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| A 749 | <p>Continued From page 200</p> <p>transportation. The bins were found wet and dusty on the inside.</p> <p>A plastic cooler was found sitting on the soiled floor in the nurse's station. The cooler was soiled on the outside with dirt and scuff marks. The cooler had a timer on the outside and a sticker in yellow that stated, "Do Not Put Platelets or Cryo in Cooler." A red sticker stated, "Maximum # of units in cooler is 10." The cooler was found with 2 units of packed red blood cells for a patient that had not yet arrived. RN #115 confirmed that there is no other place to store the blood when it comes. The cooler is left in the open nurse's station and unprotected on a dirty floor.</p> <p>The medication refrigerator was found soiled with dust and missing paint on the inside. The back wall of the refrigerator was caked in ice and unable to be cleaned properly.</p> <p>Main Emergency Room:</p> <p>Chairs in the triage area of the Main Emergency Room were found to have wooden arms and legs. The wood was worn and bare wood was exposed. The chairs could not be cleaned properly with bare wood exposed.</p> <p>On Thoracic ICU 7 Cooley A at 10:47 am on 3/25/19, in the patient nourishment room, there were dried drips and debris on the top of the cabinet drawers and there was dust on the shelves. This was observed and confirmed in an interview with Staff #10 during the tour.</p> <p>On 7 South 2 at 11:25 am on 3/25/19, the glucometer box was in need of cleaning as there</p> | A 749 | | | |

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| A 749 | <p>Continued From page 201</p> <p>was a dirty, tacky, sticky substance on top of the box, which contained items for use in patient care, such as gauze, alcohol wipes, and glucometer lancets. RN #12 observed and confirmed in an interview that the glucometer box needed cleaning.</p> <p>On 7 South 2 at 11:30 am on 3/25/19, the floor in the corners in patient rooms near the doors were dirty and in need of cleaning as there was raised debris and wax/soap/dirt residue build up in the corners and crevices of the floor. The area of the perimeter of the floor was a brownish color in contrast to the beige flooring. RN #13 observed and confirmed the floors were in need of cleaning in Bed 11, Bed 14, Bed 15, and Bed 19.</p> <p>Crash Cart #12, which was located on 24 Tower Telemetry Unit on 4/1/19 at 10:45 am, was observed to have a spill approximately 5 inches x 1 inch on the bottom shelf of the crash cart. There was dirt, dust, and an appearance of stickiness to the brown spill. There were items available for use in a patient emergency located on and next to the dirty spill. The outside of the cabinet was in need of cleaning, with dirt and dust on the horizontal surfaces of the cart. This was observed and confirmed in an interview with Staff #184 and RN #152.</p> <p>Observation on 3/27/19 at 10:15 AM of the Jamail Ambulatory Surgical Center revealed the following: There was one cart which contained dirty linen in the facility's one patient recovery room. The cart had visible dirt on it, mostly towards the bottom, and large amounts of old visible rust over the entire bottom of the cart.</p> <p>In addition, there were three more of the same type of linen carts, located in the facility's corridor.</p> | A 749 | | | |

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| A 749 | <p>Continued From page 202</p> <p>These three carts were also covered with large amounts of rust towards the bottom, as well as visible dirt. Two of these carts contained clean linen, one of the carts contained dirty linen. The carts containing clean linen were covered with clear plastic. One of the clean linen carts' plastic covering had a large rip, several feet long. This cart with the ripped plastic was directly adjacent to, and almost touching the dirty linen cart, which was not covered.</p> <p>In an interview on 3/27/19 at 10:30 AM, RN Manager-Staff #140, after seeing the carts, stated that all the linen carts were dirty, and said it was not acceptable to have any of these dirty carts in the facility. He said he was unaware of the problem. He then stated he would contact the vender to alert them of the situation, and for all future linen cart deliveries, only clean carts would be accepted for use.</p> | A 749 | | | |